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Supreme Court, U.S.
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IN THE

Supreme Court of the United States

ALPHAPHARM PTY., LTD. and GENPHARM INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This Court has long held that a party cannot be punished for what it was lawfully entitled to do. In spite of this fundamental rule-of-law, that is precisely what happened here. The district court punished Alphapharm for what it was lawfully entitled to do, and in the process may have gutted the underlying purpose of the Hatch-Waxman Act. In *BMW of North America Inc. v. Gore*, 517 U.S. 559, 573-74 (1996), this Court held that a fact finder (in that case, an Alabama state jury) has no power to punish a litigant for conduct that is lawful in that or other jurisdictions. The jury there had awarded $4 million in punitive damages against the automobile company BMW for repairing and repainting minimally damaged cars without notice to prospective buyers. But BMW could have no reason to believe that its conduct would subject it to sanctions in either Alabama or any of the other 49 states. Finding that the Alabama award constituted a due process violation, this Court reversed and remanded.

Here the Court faces a closely analogous set of facts. Alphapharm Pty., Ltd. and Genpharm Inc. (collectively "Alphapharm") challenged U.S. Patent No. 4,687,777 ("the '777 patent") under the Hatch-Waxman Amendments ("Hatch-Waxman") to the Food, Drug, and Cosmetic Act by certifying to the FDA that the compounds claimed in that patent were obvious. Hatch-Waxman allows such challenges if the patentee is provided notice of the challenge with a detailed statement of the legal and factual bases in support. Alphapharm provided that notice by pre-suit letter ("Notice Letter"), and explained that the '777 patent

was obvious over two particular prior-art references. Following trial, the district court rejected the challenge and ruled the '777 patent nonobvious. But the district court went further, finding that the challenge was in bad faith under the patent act's exceptional-case provision. The district court's principal basis for this finding was Alphapharm's reliance on additional prior-art references it adduced during pre-trial discovery. This was ***standard*** litigation conduct in a patent case—indeed in any case. Alphapharm had no cause to believe using information obtained through discovery at trial would subject it to sanctions. Just as in *Gore*, Alphapharm was punished for lawful conduct. Does the court's award of $5.4 million against Alphapharm penalize it for engaging in standard litigation conduct, and thus deprive Alphapharm of due process of law?

PARTIES TO THE PROCEEDING

This case arises from two separate challenges to the validity and enforceability of the '777 patent arising under Hatch-Waxman. *See* 21 U.S.C. § 355 et seq. Hatch-Waxman allows generic pharmaceutical companies, such as Alphapharm, to certify their intent to seek marketing approval of a brand-name drug, so long as they certify that any patent listed by the brand name as covering that drug, or a method of its use, is not infringed, invalid, or unenforceable. In return, Hatch-Waxman allows the patent holder to file an infringement proceeding against the company seeking such marketing approval.

Alphapharm certified that the compounds claimed in the '777 patent were obvious, and thus invalid, over the prior art. Mylan Laboratories, Inc. (n/k/a Mylan Inc.), Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively, "Mylan") also certified that the '777 patent was obvious. Respondents Takeda Chemical Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. (collectively "Takeda") sued Alphapharm and Mylan in the Southern District of New York for infringement of the '777 patent.

The case was tried in January 2006 before the bench. The district court ruled that the '777 patent was valid and enforceable. On September 20, 2006, the district court ruled the case exceptional, finding that Takeda was entitled to recover its attorneys' fees incurred to respond to these challenges. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 459 F. Supp. 2d 227, 252 (S.D.N.Y. 2006). (A27-80.) On March 21, 2007, the district court quantified the amount of the fees award, which

the court apportioned between Alphapharm and Mylan. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, Nos. 03-8253, 04-1966, 2007 WL 840368, at *1 (S.D.N.Y. Mar. 21, 2007). (A81-117.) Alphapharm and Mylan appealed, and the Federal Circuit affirmed the award of fees on January 23, 2009. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 549 F.3d 1381, 1391 (Fed. Cir. 2008) (A1-26.)

CORPORATE DISCLOSURE STATEMENT

The parent corporation and/or publicly held company that owns 10% or more of the stock of Petitioners Alphapharm Pty., Ltd. and Genpharm Inc. is Mylan, Inc. (Since the trial and appeal, Mylan, Inc. acquired Alphapharm Pty., Ltd. and Genpharm Inc.)

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Alphapharm respectfully petitions for a writ of certiorari to reverse the district court's finding of exceptional case and the Federal Circuit's January 23, 2009 affirmance of that finding.

OPINIONS BELOW

The Federal Circuit's opinion is reported at *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 549 F.3d 1381 (Fed. Cir. 2008) and is set forth in the appendix at A1-26. The opinion of the United States District Court for the Southern District of New York finding the case exceptional is reported at *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 459 F. Supp. 2d 227 (S.D.N.Y. 2006) and is set forth at A27-80. The district court's quantification of the attorneys' fees Alphapharm was ordered to pay is reported at *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.* Nos. 03-8253, 04-1966, 2007 WL 840368 (S.D.N.Y. Mar. 21, 2007), and is set forth at A81-117.

JURISDICTION

The Federal Circuit entered judgment on December 8, 2008. (A1.) The Federal Circuit denied Alphapharm's petition for rehearing en banc on January 23, 2009. (A118-19.) This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

The district court sanctioned Alphapharm $5.4 million in Takeda's attorneys fees because, in the district court's view, Alphapharm's challenge to the '777 patent was baseless. This finding was erroneous and deprived Alphapharm of due process. The district court concluded baselessness largely because Alphapharm did not rely solely on the position and proof it first offered in its pre-suit Notice Letter. Instead, Alphapharm—like any litigant would—relied at trial on information it obtained from Takeda from discovery under the Federal Rules of Civil Procedure. No other court had ever concluded that a deviation in legal theories or facts first alleged in a pre-suit Notice Letter would subject the patent challenger to pay the other side's attorney's fees. To the contrary, district courts have treated the requirement of such pre-suit notice simply as a means by which a patentee can protect his interests by conducting further investigation and, if necessary, filing suit. Alphapharm could never have foreseen that its lawful reliance on the Federal Rules of Civil Procedure would subject it to sanctions. Nor could Alphapharm have foreseen the result during the pendency of the case. Takeda never brought—indeed could not bring—a motion for sanctions pursuant to Rule 11 of the Federal Rules of Civil Procedure. Nor did Takeda (or the district court sua sponte) bring a sanctions motion for vexatious conduct under 28 U.S.C. § 1927. The failure to do so undermines the legitimacy of the district court's new-found findings of "litigation misconduct." (A50-63.)

Finally, the district court improperly imputed to Alphapharm knowledge of what the district court found

only after hearing Takeda's evidence—based largely on information until then withheld from the public—at trial. According to the district court, Takeda presented compelling evidence of commercial success of Actos®. Because Alphapharm knew that Actos® enjoyed significant sales, the court reasoned that Alphapharm should have addressed and refuted this evidence in its *pre-suit* Notice Letter. But Alphapharm had no obligation to do so under the law. Commercial success is an affirmative defense, which the patentee raises, not the challenger. Such defenses require extensive discovery and cannot be intelligently addressed before discovery is taken. For example, the defense of commercial success requires the patentee to demonstrate that the product covered by the patent enjoys success in the marketplace because of its patented features rather than factors such as clever marketing or brand recognition. To have addressed the issue, Alphapharm would have needed information on what factors other than patented features may have influenced sales, such as market position, distribution rights, salespersons, and marketing budgets. This information is not in the public domain, but rather rests exclusively with Takeda.

Left to stand, the district court's award (and the Federal Circuit's decision to affirm) seriously undermine the incentives Congress intended when it passed the Hatch-Waxman Act. The legislation was supposed to encourage generic pharmaceutical companies to "make lower cost generic drugs available more quickly." H.R. Rep. No. 108-181, at 9 (2003). But generic challengers may now, in effect, be limited to the allegations made in their pre-suit Notice Letter,

affording only the patentee the advantages of discovery. Moreover, generic challengers must now speculate on each and every potential defense a patentee might raise, foregoing otherwise valid challenges to a patent for fear of having sanctions imposed at the end of the case. These quite substantial policy considerations favor granting certiorari.

I. The District Court Decision Finding the Case Exceptional

Following limited written submission from the parties, the district court found the case "exceptional." (A30.) Several major legal errors led the district court to this conclusion.

Most relevant here, the district court erroneously believed Alphapharm's Notice Letter—***a presuit document***—forever barred Alphapharm from aiding its trial presentation with the discovery it had obtained from Takeda. According to the district court:

> What is truly exceptional here is the cascade of attacks each defendant made on the '777 patent. If the defendants had simply pursued the theories presented in their [Notice Letters], the cost of litigation would have been far lower and a simple award of the lodestar calculation may have been warranted . . . In each instance, the [Notice Letter] was so lacking in merit that it was entirely abandoned by the time of trial.

(A109.) But the court was simply wrong in concluding that Alphapharm abandoned the allegations it made in

its Notice Letter. Throughout the case, Alphapharm never abandoned the assertions it made in the Notice Letter that the compounds claimed in the '777 patent were obvious over an extremely close prior-art compound. The same "trial by Notice Letter" error led the district court to dismiss Alphapharm's reliance on other Takeda patents and file histories which became relevant during the course of discovery. According to the district court, "Alphapharm was under an obligation to identify these two references in its [Notice Letter.]" (A61.) But 35 U.S.C. § 282 only requires a patent challenger to identify the prior art it intends to rely on ***30 days prior to trial***—not at the outset of a patent case.

The district court also faulted Alphapharm for not addressing a defense that was never raised by the patentee before the Patent Office, namely so-called "commercial success." Generally speaking, a challenger alleging obviousness need only address affirmative defenses in a patent case (known as secondary considerations of nonobviousness) to the extent these defenses were raised before the Patent Office. *Cf. Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983) (acknowledging presumption of validity based on information before the examiner). In the Notice Letter, Alphapharm addressed the only defense that the Patent Office considered, unexpected results. Other affirmative defenses are raised in litigation by the patentee. But the district court faulted Alphapharm nonetheless: "The most important fact concerning non-obviousness, the significant commercial success of Actos® was well known to Alphapharm and required no discovery. The Statement was deficient in this regard

as well." (A50; *see also* A49; A62.) The district court was simply mistaken that this issue "required no discovery." *See, e.g., Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1150-51 (Fed. Cir. 1983) (sales figures alone, without considering other evidence such as market share, growth in market share is insufficient to establish commercial success). The relevance of commercial success to obviousness is only present where the patentee demonstrates that the patented features of the invention—rather than marketing, advertising, or brand positioning—are responsible for the success of a product the patent covers. Alphapharm had no access to Takeda's marketing and advertising documents to address the issue intelligently before the lawsuit began.

Alphapharm appealed the district court's validity ruling to the Federal Circuit.

II. The Federal Circuit's Affirmance

The Federal Circuit affirmed, affording broad deference to the factual findings of the district court. "Given the district court's familiarity with the parties and the issues and its thorough discussion of Alphapharm's certification letter and litigation strategy, we cannot say that the court committed clear error in finding this was an exceptional case . . . ." (A13.)

The Federal Circuit acknowledged that the district court faulted Alphapharm for buttressing its Notice Letter arguments with discovery obtained from Takeda. (A10) (noting "we do not believe that the district court faulted Alphapharm simply for changing its obviousness theory at trial from the theory advanced in the

Paragraph IV letter.") But the Federal Circuit overlooked the fact that the district court sanctioned Alphapharm for conduct wholly proper in a Hatch-Waxman case—indeed in any—case. No district court had ever held that a patent challenger could be sanctioned for availing itself of the discovery obtained under the Federal Rules of Civil Procedure. Nor did the Federal Circuit address the sanctions the district court imposed because Alphapharm did not address the issue of the commercial success of Actos®, a ***defense*** to a claim of obviousness irrelevant in an opening pleading.

Alphapharm moved for a petition for rehearing en banc but the Federal Circuit denied those petitions. (A118-19.)

REASONS FOR GRANTING THE PETITION

I. PUNISHING ALPHAPHARM FOR PROPER CONDUCT VIOLATED ITS RIGHT TO DUE PROCESS OF LAW

"To punish a person because he has done what the law plainly allows him to do is a due process violation of the most basic sort." *See Bordenkircher v. Hayes*, 434 U.S. 357, 363 (1978). The district court imposed just such an unfair punishment on Alphapharm, ordering it to pay $5.4 million in sanctions for ***standard*** litigation conduct. Alphapharm had no prior warning that the structural obviousness law it relied on would be ignored by the district court and the Federal Circuit. Nor could Alphapharm know that using discovery obtained from Takeda under the Federal Rules would trigger an award of sanctions for allegedly "shifting theories." There was

never any shift in Alphapharm's position. A party's use of trial proofs obtained in discovery hardly amounts to conduct that is either egregious or vexatious.

This Court faced a similar situation in *BMW of North America v. Gore*, though in the context of the relationship between the federal government and the states. 517 U.S. at 562-63. In *Gore*, Gore sued BMW for compensatory and punitive damages alleging that BMW's failure to disclose the repainting of his new car and pre-delivery damage constituted fraud under Alabama law. *Id.* at 563. An Alabama jury found BMW liable for compensatory damages of $4,000, but also assessed $4 million in punitive damages. *Id.* at 565. The trial court refused to set the punitive damages aside on due process grounds. The Alabama Supreme Court affirmed, but reduced the punitive damages award to $2 million because the jury had improperly computed the amount of punitive damages. *Id.* at 566-67. This Court reversed, holding that Alabama did "not have the power . . . to punish BMW for conduct that was lawful where it occurred and that had no impact on Alabama or its residents. Nor may Alabama impose sanctions on BMW in order to deter conduct that is lawful in other jurisdictions." *Id.* at 572-73.

Just as in *Gore*, the award of $5.4 million amounted to "a punitive sanction that is tantamount to a severe criminal penalty" for otherwise lawful conduct. *Id.* at 585. This Court should grant Alphapharm's petition and reverse the district court's award.

A. Alphapharm Could Not Know That Using Discovery Would Lead to Sanctions

The decision to use discovery to enhance a Hatch-Waxman case first delineated in a presuit Notice Letter is anything but "exceptional." *Aptix Corp. v. Quickturn Design Sys.*, 269 F.3d 1369, 1375-76 (Fed. Cir. 2001) (holding exceptional case because of ***unconscionable*** conduct during discovery). Generic challengers—forced to certify the invalidity of a patent without the benefit of access to confidential documents—must use discovery to develop their cases. Indeed, patent law specifically envisions that outcome. Section 282 requires a challenger to notify the patentee of the prior art the challenger expects to rely on—not at the outset—but ***within 30 days of the trial itself***. 35 U.S.C. § 282. Alphapharm complied with the statute. The district court's decision to sanction Alphapharm for relying on additional prior art not only renders that statute nugatory, but unfairly penalized Alphapharm for following the rules applicable to ***all*** patent cases.

Rules 26 through 37 of the Federal Rules of Civil Procedure provide to ***both*** parties in a litigation broad discovery "regarding any nonprivileged matter that is relevant to any party's claim or defense . . . ." Fed. R. Civ. P. 26(b)(1). The district court awarded sanctions against Alphapharm for utilizing these discovery rules to respond to Takeda's nonobviousness contentions. While the Hatch-Waxman Amendments require a pre-suit "detailed statement" from a generic challenger, that statement does not limit the challenger from amplifying its case through discovery. Indeed, Hatch-Waxman cases do not differ from other patent

cases. *Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1379 (Fed. Cir. 2007). Patent challengers as well as patentees must be able to develop facts and refine legal theories. *See, e.g., O2 Micro Int'l Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1365 (Fed. Cir. 2006) (discovery in all patent cases "allows the defendant to develop facts to support its defenses").

1. Generics often prevail on legal theories first presented after discovery

Moreover, it is common for a generic challenger, following access to the patentee's confidential documents, to use the evidence gained in discovery to refine or alter its invalidity defenses. For example, in *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 960 (Fed. Cir. 2001), the generic challenger certified as to the invalidity of the patent covering the drug Prozac®. But the winning invalidity theory—double patenting—was developed during discovery. *Id.* at 969-72. In other instances, the generic challenger prevailed on a previously unasserted invalidity theory. For example, in *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1303 (Fed. Cir. 2007), involving the drug Altace®, the generic challenger prevailed on an obviousness defense different from that asserted in its pre-suit notice letter, and developed during discovery. *Id.* at 1302-03. Generic challengers prevailed in similar ways in challenges to the drugs Ditropan XL® and Imodium Advanced®. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1295-97 (Fed. Cir. 2006); *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1370 (Fed. Cir. 2003).

2. Alphapharm could not have known that adding defenses would subject it to sanctions

The Hatch-Waxman Act requires generic challengers to serve a pre-suit Notice Letter so that a patent challenge is sufficiently "concrete" to secure federal jurisdiction. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004). Before the district court's finding of exceptional case here, no court had ever held that a patent challenger was bound at trial by the allegations in the Notice Letter. Rather, the Notice letter need only alert the patentee to the possibility of infringement by the generic applicant so that "the patent owner can protect its interest in its patents by filing a patent-infringement action." *See Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99-8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 6, 2000). Indeed, since the award, at least one other court has squarely refused to accept the proposition that deviating from a notice letter at trial renders the case exceptional under § 285. In *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 04-754, 2007 WL 4300155, at *7-11 (D.N.J. Dec. 5, 2007), generic challenger Teva's notice letter failed to make out a prima facie case of invalidity. And just as Alphapharm is alleged to have done, Teva dropped certain arguments at trial and adduced additional prior art after having the benefit of discovery. *Id.* at *10-11. Yet, the court there refused to impose sanctions. *Id.* at *11.

B. Alphapharm Had No Reason to Attempt to Rebut Potential Affirmative Defenses in the Notice Letter

The Federal Circuit noted that the district court correctly found that Alphapharm's Notice Letter would amount to litigation misconduct if it were baseless and failed to establish a prima facie case of invalidity. (A13.) But the district court sanctioned Alphapharm in part because Alphapharm's Notice Letter failed to address commercial success—a potential ***defense*** to Alphapharm's obviousness assertions. (A49-50.) The Federal Circuit panel failed to address this error.

First, the secondary indicia of nonobviousness are simply not part of a prima facie case of invalidity. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006) (holding that the secondary indicia, including commercial success, ***rebutted*** any showing of prima facie obviousness). The patentee—not the challenger—bears the burden on this issue. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). The law did not require Alphapharm to anticipate and rebut every potential patentee defense in its Notice Letter using only publicly available information.

Moreover, Alphapharm could hardly have acted in bad faith for failing to address an issue it could not reasonably address without discovery. Commercial success is relevant only where "the [patentee's] sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the

patented subject matter." *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996). Alphapharm could not possibly determine what was driving the sales of Actos® until discovery was had. Such information is maintained as confidential. Notably, Alphapharm's expert economist—armed with the information Alphapharm obtained in discovery—testified that non-patented features, including market forces, an aggressive marketing campaign, and unusual giveaways accounted for the qualified success of Actos®. (SA1-48.)

II. REVERSAL OF THE RULING WILL RESTORE A LEVEL PLAYING FIELD BETWEEN GENERIC AND BRAND PHARMACEUTICAL COMPANIES

Alphapharm, and its co-defendant Mylan will not be the only parties affected by the district court's sweeping ruling, now affirmed. The award of sanctions on these grounds cannot help but to chill and deter future generic filings. Generic companies may not file a paragraph IV certification unless confident that the case could be won ***without pretrial discovery***. The purpose of the Hatch-Waxman Amendments—to speed delivery of inexpensive medicine to patients—will be seriously undermined. S. Rep. No. 105-36(I), at 125 (1997).

Those generics that do mount a patent challenge will be forced to self-censor bringing additional theories to bear at trial no matter what the other side's confidential documents reveal. Trials are a search for the truth, not a rote presentation limited to publicly available documents. *See Portuondo v. Agard*, 529 U.S. 61, 73 (2000). Nor should a trial have the same breadth as the pretrial discovery. *See* Fed. R. Civ. P. 26(b) advisory

committee notes (the 1946 amendments "make clear the broad scope of examination and that it may cover not only evidence for use at trial but also inquiry into matters in themselves inadmissible . . . .").

The ruling will also create perverse incentives. The district court chose to sanction Alphapharm for dropping a theory based on what it had learned in discovery (A47-48.) The Federal Circuit's affirmance of that ruling will now only encourage generic challengers to put in and maintain every possible argument at trial, for fear that narrowing the issues will be used against them in a later fees application.

Left to stand, the court's ruling arms the brand-name company with the full use of the broad discovery set forth in the Federal Rules of Civil Procedure while forcing a generic company to subject itself to sanctions for availing itself of the same Rules. Such a result is clearly contrary to law. "[T]here is and should be no difference in the standards applicable to patentees and infringers who engage in bad faith litigation." *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 811 (Fed. Cir. 1990). Reversing the district court's ruling will restore a level playing ground. *See Doubleday & Co. v. Curtis*, 763 F.2d 495, 503 (2d Cir. 1985) (reversing dismissal of claim where dismissal "violated the spirit of both the United States Constitution [due process clause] and the Federal Rules of Civil Procedure [Rule 8(c)].").

CONCLUSION

Alphapharm respectfully requests that this Court grant the petition for a writ of certiorari, and reverse the judgment of the Federal Circuit.

Dated: May 26, 2009

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED DECEMBER 8, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007-1269, 07-1270

TAKEDA CHEMICAL INDUSTRIES, LTD., and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs-Appellees,

v.

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., and UDL LABORATORIES, INC.,

Defendants-Appellants,

and

ALPHAPHARM PTY., LTD. and GENPHARM, INC.,

Defendants-Appellants.

DECIDED: December 8, 2008

Appendix A

Before LOURIE, RADER, and BRYSON, *Circuit Judges.*

Opinion for the court filed by LOURIE, *Circuit Judge.* Opinion concurring in part and concurring in the result in part filed by BRYSON, *Circuit Judge.*

Alphapharm Pty. Ltd. and Genpharm, Inc. (collectively, "Alphapharm") and Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively, "Mylan") appeal from the final judgment of the United States District Court for the Southern District of New York. On September 20, 2006, the court granted a motion by plaintiff and patentee Takeda Chemical Industries, Ltd. and its affiliate Takeda Pharmaceuticals North America, Inc. (collectively, "Takeda") to find the case relating to Hatch-Waxman challenges made by Alphapharm and Mylan in connection with Takeda's U.S. Patent 4,687,777 ("the '777 patent") to be exceptional and to award attorney fees. *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 459 F.Supp.2d 227 (S.D.N.Y.2006) ("September Opinion"). On March 21, 2007, the court quantified the attorney fees, expenses, and expert fees, awarding Takeda $11,400,000 from Mylan and $5,400,000 from Alphapharm, with interest. *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, Nos. 03-8253, 04-1966, 2007 WL 840368 (S.D.N.Y. Mar. 21, 2007) ("March Opinion"). Because we conclude that the district court did not clearly err in finding that this was an exceptional case because of the misconduct of Mylan and Alphapharm and did not abuse its discretion in awarding attorney fees, we affirm.

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BACKGROUND

The '777 patent covers the anti-diabetic drug pioglitazone, for which Takeda has enjoyed commercial success under the name ACTOS®. Alphapharm and Mylan are two generic drug companies that sought approval to produce generic versions of pioglitazone under the Hatch-Waxman Act. That legislation provides the mechanism for a generic drug company to file an abbreviated new drug application ("ANDA"). An ANDA announces the intention of the filer to sell a bioequivalent form of a drug when approved by the FDA, and the filer makes a certification regarding existing patents covering the drug and its use. 21 U.S.C. § 355(j) (2006). Both Mylan and Alphapharm chose to make certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV"), certifying that the '777 patent was invalid for obviousness. In response, Takeda sued Alphapharm and Mylan for infringement.

At trial, Alphapharm and Mylan each changed the focus of their invalidity arguments from those in their certification letters. Alphapharm pointed to a compound referred to as compound b, which Takeda disclosed in U.S. Patent 4,287,200 ("the '200 patent") and in a 1982 scientific article[1] ("Sohda II"), as evidence that pioglitazone was structurally obvious at the time the

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1. T. Sohda et al., *Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1-Methylcyclohexylmethoxy)-benzyl] thiazolidine-2, 4-dione (ADD-3878) and its Derivatives*, 30 Chem. Pharm. Bull. 3580 (1982).

invention was made. Mylan advanced an inequitable conduct argument based on alleged misrepresentations by Takeda to the Patent and Trademark Office ("PTO"). On February 21, 2006, after an extensive bench trial, the district court held the invention of the '777 patent to be nonobvious and enforceable. *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 417 F.Supp.2d 341 (S.D.N.Y.2006). The district court entered final judgment on March 13, 2006, and we affirmed the district court in two separate appeals. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed.Cir.2007); *Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., Ltd.*, No. 06-1364, 2007 U.S.App. LEXIS 15883 (Fed. Cir. June 28, 2007).

Takeda then moved for an award of attorney fees against both Mylan and Alphapharm on the theory that this was an exceptional case. When a patent has been infringed by the filing of an ANDA, 35 U.S.C. § 271(e)(4) provides for the grant of attorney fees under 35 U.S.C. § 285, which in turn allows the court to award reasonable attorney fees to a prevailing party in exceptional cases. Takeda contended that Mylan and Alphapharm each lacked a good faith basis for their Paragraph IV letters and engaged in misconduct throughout the litigation.

On September 20, 2006, the district court agreed with Takeda in an opinion that discussed the Paragraph IV letters and litigation conduct of Alphapharm and Mylan in the same thorough manner as the court's previous decision regarding the validity of the '777 patent. Regarding Alphapharm, the court held that the

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Paragraph IV certification letter was "so devoid of merit and so completely fail[ed] to establish a prima facie case of invalidity that it must be described as 'baseless.' " September Opinion, 459 F.Supp.2d at 235. The court discussed at length how Alphapharm's argument at trial focused on compound b as the lead compound for future research, whereas Alphapharm's certification letter focused on two other compounds and contained scientific errors. The court also analyzed what it saw as Alphapharm's litigation misconduct, which mainly consisted of a shifting theory of obviousness that did not explain why compound b would have been identified as the lead compound. As a result, the court found that this was "the exceptional case where an examination of the totality of the circumstances amply justifies, indeed compels, the award of attorneys' fees." *Id.* at 245.

Similarly, the court held that Mylan's certification letter was filed in bad faith and with no reasonable basis to claim the '777 patent invalid. The court discussed how Mylan argued in its Paragraph IV letter that the invention of pioglitazone was obvious based on Takeda's disclosure of a compound in the '200 patent and Sohda II (referred to as compound 16 and compound 14, respectively) only to abandon this theory entirely during the litigation. In addition, the court discussed Takeda's numerous allegations of litigation misconduct committed by Mylan in its pursuit of an inequitable conduct claim, which principally addressed Takeda's representations to the PTO regarding a different compound disclosed in the prior art, compound 3894. The court also found that the inequitable conduct claim

was "always frivolous" and unsupported, as Mylan did not present any evidence that Takeda hid or misrepresented any information to the PTO. *Id.* at 249. The court concluded that the totality of the circumstances, including other instances of Mylan's untimely conduct, justified the award of attorney fees against Mylan as well.

On March 21, 2007, the district court quantified the fees at $16,800,000, with Alphapharm to pay $5,400,000 and Mylan, $11,400,000. In assessing the amount of the award, the court stated that the attorneys for Takeda did uniformly excellent work in a complex and contentious litigation. When allocating the attorney fees, the court accepted the division proposed by Takeda, with Mylan responsible for two-thirds of the total amount. The court also awarded Takeda its expert fees under its inherent power to impose sanctions, along with expenses and interest beginning on the date of the September Opinion.

Mylan and Alphapharm filed separate timely appeals from the district court's judgment. The appeals were consolidated on December 17, 2007. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

Appendix A

DISCUSSION

A. Exceptional Case Finding

35 U.S.C. § 285 provides that a trial court "in exceptional cases may award reasonable attorney fees to the prevailing party." The decision to award attorney fees is within the discretion of the trial judge, but the conclusion that a case is exceptional is a finding of fact reviewable only for clear error. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed.Cir.1989). We address the arguments of the appellants with regard to the district court's finding of an exceptional case individually.

1. Alphapharm

On appeal, Alphapharm argues that its Paragraph IV letter was not baseless under structural obviousness law. Alphapharm asserts that its certification letter made out a prima facie case of obviousness and that, contrary to what the district court held, Alphapharm was not required to explain why a skilled artisan would have identified compound b as the lead compound in its certification letter. As evidence of what it argues was a reasonable chance to succeed, Alphapharm points to Judge Dyk's concurrence in the prior decision of this court. Alphapharm also argues that the fact that its original theory did not prevail at trial falls far short of clear and convincing evidence required for the district court to find that its certification letter was baseless. Alphapharm further claims that affirming the district

court's ruling would chill challenges by generic drug companies to otherwise invalid patents by requiring the inclusion of every possible theory of invalidity in a certification letter rather than allowing an ANDA filer to develop its theories during the course of discovery. Similarly, Alphapharm argues that the district court erred in finding litigation misconduct because Alphapharm consistently argued an obviousness theory and merely honed its arguments in response to documents produced during discovery by Takeda. Alphapharm also disagrees with the court's characterization of certain of its evidence as an attempt to inject an inequitable conduct argument into the obviousness inquiry.

Alphapharm and Mylan are supported in this appeal by amicus curiae, the Generic Pharmaceutical Association, who submitted a brief and was permitted to orally argue before the court. Amicus argues that failure to reverse the district court's finding of an exceptional case would deter generic applicants from presenting defenses at trial that were not included in their certification letters. Amicus asserts that changing defenses is normal conduct during litigation, especially in patent cases, when ANDA applicants prepare certification letters without the benefit of discovery. As a result, amicus argues, ANDA filers should be allowed to litigate the best available theories at trial, regardless of their inclusion in certification letters. Amicus asserts that if the district court decision stands, it will have a chilling effect on future ANDA patent challenges.

Takeda responds that Alphapharm's argument, that it should benefit from a presumption of obviousness based on structural considerations, has already been rejected by this court. In addition, Takeda points out that Alphapharm's certification letter included scientific errors and that Judge Dyk's concurrence did not address the claim of the '777 patent specific to pioglitazone, the invalidity of which was necessary for Alphapharm's success. Finally, Takeda asserts that the record amply supports the district court's finding that Alphapharm presented constantly shifting, but always baseless, obviousness arguments. That finding, Takeda argues, supports the court's conclusion that Alphapharm's obviousness theories never had a good faith basis and thus warranted an exceptional case finding.

As noted by Takeda, we have already held that the district court did not commit reversible error by refusing to apply a presumption of motivation to select compound b as the lead compound based on structural obviousness. *See Takeda*, 492 F.3d at 1360. Accordingly, although Alphapharm made brief reference to compound b in its Paragraph IV letter, it failed to provide any reason in its Paragraph IV letter to identify compound b as the lead compound and thus did not make out a prima facie case of obviousness based on the structural similarity between compound b and pioglitazone. Any support Alphapharm hopes to gain from Judge Dyk's concurrence is moreover lacking, as his opinion addressed the possible overbreadth of two claims in the '777 patent and not, as Alphapharm claims, structural

obviousness based on the prior disclosure of compound b. *Id.* at 1364 (Dyk, J., concurring).

Furthermore, although it seems reasonable to expect assertions of invalidity based on prior art to remain relatively consistent as the prior art should be known when the certification of invalidity is made, we do not believe that the district court faulted Alphapharm simply for changing its obviousness argument at trial from the theory advanced in the Paragraph IV letter. Rather, the court methodically examined a number of shortcomings in Alphapharm's Paragraph IV letter, which were made obvious by Alphapharm's "constantly shifting set of arguments," that supported the finding that the certification was baseless. September Opinion, 459 F.Supp.2d at 236. The court noted the stark contrast between Alphapharm's focus on compound b as the lead compound at trial with its discussion in the certification letter of two other compounds disclosed in Sohda II and how, as a result, Alphapharm "did not grapple with the many impediments evident in Sohda II for choosing compound (b) as a lead compound." *Id.* The court also catalogued scientific errors in Alphapharm's certification letter that the court saw as "insidious" and as underscoring that Alphapharm "did not act with due care or in good faith" in filing its certification. *Id.* at 237. The court found that other assertions in Alphapharm's Paragraph IV letter were baseless because of undisputed evidence of pioglitazone's superiority and that Alphapharm abandoned these arguments at trial because "they were unsupportable, not because Alphapharm made a tactical decision

regarding which argument should be emphasized at trial." *Id.* at 238. The court concluded that the deficiencies in Alphapharm's Paragraph IV letter were "so glaring" that they highlighted that Alphapharm "acted in bad faith in filing its Paragraph IV certification." *Id.* at 239.

The court also discussed in depth what it saw as Alphapharm's litigation misconduct. The court traced the many iterations of Alphapharm's theory of obviousness and pointed to Alphapharm's "utter failure" to account for the identification of compound b as the lead compound as required under structural obviousness law. *Id.* at 241. The court reasoned that Alphapharm had over two years to develop its obviousness arguments in its Paragraph IV letter, and its failure to explain "why its Statement was so flawed and why its description of obviousness went through such a dramatic evolution" was "overwhelming" evidence of Alphapharm's bad faith. *Id.* at 243. Finally, the court discussed assertions made by Alphapharm that were unrelated to the obviousness claim and "created confusion, wasted valuable court time, and increased the burden of the litigation on the parties." *Id.* When considering the totality of the circumstances, the court stated bluntly, "This case was not close." *Id.* at 244. The court's conviction in its findings could hardly be clearer.

A number of different circumstances may support the finding of an exceptional case, including "vexatious or unjustified litigation" or "frivolous suit," of which there must be clear and convincing evidence. *Beckman,*

892 F.2d at 1551. Indeed, one of the purposes of § 285 is to prevent " 'gross injustice' when the accused infringer has litigated in bad faith." *Id.* at 1552. In *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*, we stated that "[t]he joint operation of §§ 271(e) and 285 require the paragraph (2) infringer to display care and regard for the strict standards of the Hatch-Waxman Act when challenging patent validity. . . . The Hatch-Waxman Act thus imposes a duty of care on an ANDA certifier." 231 F.3d 1339, 1347 (Fed.Cir.2000). Alphapharm now argues that *Yamanouchi*'s "duty of care" language lays out a simple negligence standard. Alphapharm further contends that this standard conflicts with *Beckman*, which, Alphapharm argues, establishes the far higher threshold of gross negligence. Alphapharm is incorrect on both points.

In the first place, *Beckman* does not set out a gross negligence standard. In *Beckman*, we stated that § 285 prevents "gross injustice" where a party has demonstrated "bad faith and misconduct during litigation." *Beckman*, 892 F.2d at 1553. In addition, *Yamanouchi* does not establish a simple negligence standard, nor did the district court in this case apply such a standard. Although *Yamanouchi* states that ANDA applicants owe a duty of care under the Hatch-Waxman Act, it explained that applicants fail to meet this duty when they file "baseless" certifications. 231 F.3d at 1347. Thus, *Yamanouchi* does not stand for the proposition that ANDA applicants who are merely negligent can trigger § 285.

In this case, the district court correctly found that Alphapharm's filing would amount to litigation misconduct supporting an exceptional case finding if it were "baseless" and if it "fail[ed] to present even a prima facie case of invalidity in filing the paragraph IV certification." September Opinion, 459 F.Supp.2d at 232. Thus, the trial court did not apply a simple negligence standard but found Alphapharm's filing "baseless." Moreover, the trial court found misconduct during litigation. Given the district court's familiarity with the parties and the issues and its thorough discussion of Alphapharm's certification letter and litigation strategy, we cannot say that the court committed clear error in finding that this was an exceptional case due in part to the misconduct of Alphapharm. *See Beckman*, 892 F.2d at 1552 & n. 1 (noting that the district judge was in "the best position" to monitor litigation strategy and find bad faith).

2. Mylan

On appeal, Mylan argues that the district court based its finding of an exceptional case against Mylan on conjecture rather than requiring Takeda to show clear and convincing evidence. As support for its position, Mylan points to its decision not to pursue the same arguments at trial as in its Paragraph IV letter, arguing that because Mylan's original invalidity theory was never pursued, the court had to rely on speculation in finding the certification letter baseless. Mylan also asserts that its decision to amend its defenses to include a revised obviousness claim and an inequitable conduct

claim did not constitute litigation misconduct or demonstrate bad faith because it is customary to develop defenses during discovery. Mylan argues that the fact that it ultimately did not win on these claims does not render this case exceptional. Furthermore, Mylan asserts that the district court's decision to allow Mylan to assert its inequitable conduct claim demonstrates that it was not frivolous and thus was not litigation misconduct.

Takeda responds by pointing to the district court's analysis of the evidence regarding Mylan's certification letter and litigation misconduct. Takeda notes Mylan's error in characterizing compound 14 and pioglitazone as bioisosteres in its Paragraph IV letter, which certified that pioglitazone was obvious based on the disclosure of compound 14 in the '200 patent and Sohda II. Takeda argues that this invalidity argument was so devoid of merit that Mylan did not pursue this obviousness claim in discovery and abandoned it before trial. Takeda then argues that Mylan suddenly asserted a revised obviousness theory centering on compound 3894 that was similarly fraught with scientific errors. With regard to Mylan's inequitable conduct claim, Takeda asserts that this claim was also frivolous, as Mylan completely failed to present any evidence of intent to deceive the PTO, and notes that the court specifically stated that allowing Mylan to amend its defenses to include inequitable conduct did not mean that the amendment was timely or meritorious.

We conclude that the court did not commit clear error in finding that Mylan's misconduct contributed to this being an exceptional case. In fact, Mylan's invalidity argument in its certification letter appears even more baseless than Alphapharm's. Mylan certified that pioglitazone was rendered obvious because Takeda had already disclosed compound 14, which had high efficacy, and simply replaced its benzene ring with a pyridine ring, which it described as a bioisostere, to create pioglitazone. But Mylan's Rule 30(b)(6) designee testified that no reason existed to choose compound 14 as the lead compound; Takeda's expert emphatically disagreed with the assertion that benzene and pyridine rings are bioisosteres; and Alphapharm's expert testified that the properties of compound 14 taught nothing with respect to pyridines. We find it unsurprising, therefore, that the district court characterized Mylan's defense of the merits of its Paragraph IV letter as "utterly frivolous." September Opinion, 459 F.Supp.2d at 247. In light of the scientific errors present in Mylan's certification letter, the fact that the court was unmoved by Mylan's decision not to pursue this obviousness claim at trial can hardly be deemed clear error. We believe the court had ample reason to hold that Mylan's certification letter was filed in bad faith and with no reasonable basis to claim the '777 patent invalid.

Similarly, the finding that Mylan engaged in litigation misconduct was well-supported and explained by the district court. The court deemed Mylan's later argument based on compound 3894 to be "extremely misleading." *Id.* at 247. In addition, the court discussed

Takeda's seven asserted separate grounds for litigation misconduct committed by Mylan in its pursuit of an inequitable conduct claim. As Takeda points out, the district court stated that "its decision to allow Mylan to bring its claim of inequitable conduct was absolutely not a finding that it was timely or meritorious." *Id.* at 249. Accordingly, the court found that the inequitable conduct claim was "always frivolous" and unsupported, as Mylan did not present any evidence that Takeda hid or misrepresented any information to the PTO. *Id.* We do not find persuasive Mylan's argument that the district court took issue with the mere fact that Mylan changed its theory of invalidity and then lost. Rather, the court determined that Mylan's initial certification letter was completely baseless and that the claims Mylan offered as substitutes were similarly frivolous. In short, the district court, which was in the best position to evaluate the entire strategy pursued by Mylan, did not commit clear error in finding litigation misconduct.

Finally, we find the "chilling" argument regarding ANDA filers advanced by Alphapharm and Mylan to be unpersuasive, despite the support provided by the amicus filing of the Generic Pharmaceutical Association. In making a Paragraph IV certification, appellants are statutorily required to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid." 21 U.S.C. § 355(j)(2)(B)(iv)(II) (2006). It is clear from the district court's opinion that it was not faulting Alphapharm or Mylan for the act of filing an ANDA that challenged the pioglitazone patent, nor did it limit the filers to the theories raised in their

certification letters. Rather, the district court found the case exceptional based on the specific circumstances involved in this case, *viz.*, baseless certification letters compounded with litigation misconduct. In fact, the court addressed the deterrence argument directly:

> There is no basis to find that this award of fees will deter ANDA filings and litigation. This award addresses baseless ANDA filings and the pursuit of frivolous ANDA litigation in bad faith and other litigation misconduct. The Hatch-Waxman Act cannot be read to immunize such conduct.

September Opinion, 459 F.Supp.2d at 251. Given the court's specific articulation that its ruling was directed toward baseless ANDA filings and litigation in bad faith, we decline to disturb the court's finding of an exceptional case as potentially chilling non-frivolous ANDA filings under the Hatch-Waxman Act. Well-supported filings challenging the validity and infringement of patents owned by an NDA holder should not raise the specter of an unjustified holding of an exceptional case.

B. Amount of Award

If a district court has not clearly erred in finding a case exceptional, we review the award of attorney fees for an abuse of discretion. *Yamanouchi,* 231 F.3d at 1346. The abuse of discretion standard also applies to the district court's exercise of its inherent power to award sanctions. *Amsted Indus. Inc. v. Buckeye Steel*

Castings Co., 23 F.3d 374, 379 (Fed.Cir.1994). Under that standard, we will affirm a district court unless its decision was "clearly unreasonable, arbitrary or fanciful, or based on an erroneous conclusion of law or fact." *Yamanouchi*, 231 F.3d at 1346.

Appellants argue that Takeda's award request was excessive for a litigation that lasted just two years and culminated in a nine-day trial. They point to Takeda's billing entries and expenses as excessive and inadequately supported in arguing that the district court abused its discretion by not reducing the award from the requested amount. Mylan also argues that the court abused its discretion in failing to consider opinions of Mylan's experts regarding the reasonableness of the award and that the court had no basis for its two-thirds allocation of the fee award to Mylan. Finally, both Alphapharm and Mylan assert that the additional sanctions of expert fees and expenses were unjustified because there was no evidence of fraud or abuse of the judicial process.

Takeda responds that the district court examined all relevant factors in determining the amount of attorney fees, including the time entries and staffing of the litigation. Takeda also points to the court's analysis of Mylan's expert declarations and its reasoning for the allocation of the award in asserting that both decisions fell within the court's discretion. With regard to the expert fees, Takeda argues that the court had the discretion to impose a sanction because of the appellants' bad faith and vexatious conduct during the litigation.

Although the award of the total amount of a fee request is unusual, we have stated that such an award may be imposed and affirmed. *See Beckman,* 892 F.2d at 1553 ("[W]e can certainly imagine a case in which litigation misconduct would justify an award of attorney fees for the entire litigation."). That determination lies within the discretion of the trial judge, "who is in the best position to know how severely [a party's] misconduct has affected the litigation." *Id.* Here, the district court left no doubt as to its opinion of the litigation and work performed by counsel. The court characterized the work of Takeda's counsel as "uniformly excellent" and determined that the attorney fee award was reasonable. March Opinion, 2007 WL 840368, at *4. Indeed, the court indicated that an even higher award would have been justified. The court found that none of the attacks on the size of the fee award had merit, and the court also gave specific reasons for disregarding Mylan's purported expert opinions, including a lack of experience on the part of the declarants with both the present litigation and patent litigation as a whole. Furthermore, the court explained its allocation of two-thirds of the fee burden to Mylan because it acted as lead defense counsel for discovery of the obviousness claims and then added considerably to the complexity of the case with an untimely assertion of an inequitable conduct claim. Given the court's reasoned analysis and familiarity with the litigation, we do not believe that the court abused its discretion with its award of attorney fees and related expenses. *See Mathis v. Spears,* 857 F.2d 749, 759 (Fed.Cir.1988) (allowing for the award of expenses under § 285).

As for the award of expert fees, a district court may invoke its inherent power to impose sanctions in the form of reasonable expert fees in excess of what is provided for by statute. *See Chambers v. NASCO, Inc.*, 501 U.S. 32, 50, 111 S.Ct. 2123, 115 L.Ed.2d 27 (1991); *Mathis*, 857 F.2d at 759 (noting that "full expert witness fees have been awarded, without specific statutory authorization, upon a finding of bad faith"). The use of this inherent power is reserved for cases with "a finding of fraud or abuse of the judicial process." *Amsted*, 23 F.3d at 378. While it is true that the appellants' conduct did not amount to fraud, courts may use sanctions in cases involving bad faith that cannot be otherwise reached by rules or statutes. *See Chambers*, 501 U.S. at 46, 111 S.Ct. 2123 (discussing cases). Here, the court below could not award expert fees under § 285, but it was entitled to use its inherent powers to award Takeda the expert fees. Because of the court's numerous articulations of appellants' bad faith and vexatious litigation conduct, we cannot say that the decision to do so was an abuse of discretion.

We have considered the other arguments raised by appellants and find them unpersuasive.

CONCLUSION

Accordingly, we affirm the district court's finding of an exceptional case and the award to Takeda of $16,800,000 for attorney fees, expenses, and expert fees, plus interest.

AFFIRMED

BRYSON, Circuit Judge, concurring in part and concurring in the result in part.

I agree that the district court did not abuse its discretion in awarding Takeda attorney fees. As a practical matter, the task of determining whether a case is "exceptional" within the meaning of 35 U.S.C. § 285 so as to justify an award of attorney fees is necessarily committed almost entirely to the judgment of the district court. A district judge who has lived with a case and the lawyers for an extended period (four years in this case) is infinitely better situated than we are to make the kind of holistic judgments about the parties' conduct of the litigation that are required to assess whether the case should be treated as exceptional and whether fees should be awarded. Where the trial court applies the proper legal standards and conducts a thorough review of the circumstances bearing upon the section 285 inquiry, there is little room for a reviewing court to second-guess the trial court's judgment. In this case, the trial judge's analysis was thorough and her finding that the case was exceptional was not based on the application of an erroneous legal standard. Under these circumstances, I agree with my colleagues that we cannot overturn the court's judgment as to the applicability of sanctions under section 285.

With respect to the portion of the award attributable to expert witness fees, I would uphold the award, but on a narrow ground and with reservations. As the district court correctly understood, expert witness fees cannot be awarded as a sanction under

section 285. For that reason, the court invoked the court's inherent authority to justify the award of expert witness fees. *See Chambers v. NASCO, Inc.*, 501 U.S. 32, 111 S.Ct. 2123, 115 L.Ed.2d 27 (1991). While we have recognized that district courts can award expert fees in patent cases under their inherent authority, we have made clear that "not every case qualifying as exceptional under section 285 will qualify for sanctions under the court's inherent power." *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 23 F.3d 374, 378 (Fed.Cir.1994). To the contrary, a district court may resort to its inherent power to impose sanctions only in those highly unusual cases in which the pertinent statutory remedies are plainly inadequate to address the misconduct at issue. *Amsted*, 23 F.3d at 379 ("The court should resort to its inherent power only where the rules or statutes do not reach the acts which degrade the judicial system. . . . [C]ourts should only resort to further sanctions when misconduct remains unremedied by those initial tools."); *see also Martin v. Brown*, 63 F.3d 1252, 1265 (3d Cir.1995) ("inherent power should be reserved for those cases in which the conduct of a party or an attorney is egregious and no other basis for sanctions exists"); *In re Rimsat, Ltd.*, 212 F.3d 1039, 1048 (7th Cir.2000). Routine use of inherent authority to impose sanctions in addition to those authorized by applicable statutes risks contravening Congress's judgment as to what sanctions are appropriate for particular misconduct. *See, e.g., Corley v. Rosewood Care Ctr., Inc.*, 142 F.3d 1041, 1059 (7th Cir.1998); *Klein v. Stahl GMBH & Co. Maschinefabrik*, 185 F.3d 98, 110 n. 10 (3d Cir.1999). Where, as here, the district court's award of attorney

fees under section 285 and expert witness fees under its inherent authority are predicated on the same conduct, the district court must offer a reasoned explanation for why the award of attorney fees and expenses under section 285 is not a sufficient sanction for the conduct in question. *See Corley*, 142 F.3d at 1058-59 ("The court also should have explained why Rule 11 was inadequate to serve the court's purposes. . . .").

There are obviously different degrees of unjustifiable conduct, and the district court must identify the considerations that justify distinguishing "between inappropriate conduct redressable under 35 U.S.C. §§ 284, 285 and egregious conduct which justifies resort to the inherent power to sanction." *Amsted*, 23 F.3d at 378. The problem is that the standard required to justify invoking the court's inherent authority to impose sanctions is extremely vague. The standard articulated by the Supreme Court permits a court to invoke its inherent powers if the court determines "that fraud has been practiced upon it, or that the very temple of justice has been defiled." In this case, there is no suggestion that the defendants have engaged in fraudulent conduct. Instead, the court upholds the award of expert witness fees based on an abuse of judicial process, i.e., the "defiling the very temple of justice" rationale. Unfortunately, while that metaphor is colorful, it does not make for a very useful legal standard. What I take from the Supreme Court's opinion in *Chambers* and our decision in *Amsted* is that cases in which it will be considered appropriate to impose "inherent authority" sanctions in addition to those

already imposed pursuant to statute or rule will be very rare. Indeed, in *Amsted* we found that the district court's exercise of its inherent power was unjustified even though the accused infringer continued to press its defenses knowing that they were meritless, burdened the court with unnecessary motions, and violated a court order. *Amsted*, 23 F.3d at 378-79. While we acknowledged in *Amsted* that the sanctioned party had engaged in inappropriate conduct, we held that it did not constitute "egregious conduct" and "bad faith" of the sort necessary to justify resort to the inherent power to sanction. *Id.* at 379.

In this case, the district court found "overwhelming" evidence of "bad faith" by Alphapharm and found that Mylan engaged in "a host of bad faith litigation tactics, which increased the burden of this litigation enormously." The court further ruled that an award of the costs associated with Takeda's employment of experts "is particularly warranted in this case" because the defendants knew that their attacks on Takeda's patent "were groundless and would only succeed if Takeda did not expend the effort and resources necessary to shine a light on the flaws in the defendants' arguments."

In my view, it is questionable whether that explanation, even as supplemented by the court's detailed analysis in its sanctions opinion of September 20, 2006, is sufficient to meet the requirement of a satisfactory explanation for invoking the inherent authority to award expert witness fees. However, it is

not necessary to decide that issue in this case, because the district court made clear that the amount of its overall award did not depend on the award of expert witness fees. In its March 21, 2007, opinion, the court remarked that Takeda "would certainly be fairly entitled to an enhancement of about $3 million, with $2 million charged to Mylan and $1 million charged to Alphapharm" in light of Takeda's success and to "reflect the extensiveness of the misconduct here," which prolonged and increased the burden of the litigation on Takeda. Although the court did not grant the enhancement, it stated that "an enhancement to the lodestar amount will not be separately awarded" because "Takeda's expert fees are also being awarded." The court thus made clear that if it were not able to award expert witness fees, it would grant the requested enhancement of the attorney fees. For that reason, it is clear that the award of expert witness fees, even if improper, did not result in a greater total fee award than the court otherwise would have imposed if it had been limited to basing its assessment on section 285 alone.[1] I therefore concur in this court's action upholding the district court's award to Takeda. That said, however, I believe it is important to emphasize that this case

1. Several of the expenses included in the section 285 award would appear questionable as reasonable expenditures necessary to the prosecution of the case. Those include, for example, "[b]everages while waiting at airport," client dinners, and late fees for borrowed books. The appellants have not focused on those items in their briefs, however, and therefore I would not require a remand for a specific justification of those expenses.

should not be viewed as an invitation for district courts to impose "inherent authority" sanctions liberally in patent cases, and that such awards, even if appropriate in some cases, should be very much the exception and not the rule.

APPENDIX B — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK FILED SEPTEMBER 20, 2006

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

03 CIV. 8253 (DLC), 04 CIV. 1966

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs.

-v-

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., and UDL LABORATORIES, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

-v-

ALPHAPHARM PTY. LTD. and GENPHARM, INC.,

Defendants.

Appendix B

September 20, 2006, Decided
September 20, 2006, Filed

OPINION & ORDER

DENISE COTE, District Judge.

On March 10, 2006, judgment was entered following a non-jury trial in favor of plaintiff and patentee Takeda Pharmaceutical Company, Ltd. (formerly Takeda Chemical Industries, Ltd.), and its affiliate Takeda Pharmaceuticals North America, Inc. (collectively, "Takeda") and against two generic drug companies, Alphapharm Pty. Ltd. and Genpharm, Inc. (collectively, "Alphapharm") and Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively, "Mylan"), in connection with the latters' challenges brought under the Hatch-Waxman Act to Takeda's U.S. Patent No. 4,687,777 ("'777 Patent"), which protects the invention of the chemical compound known as pioglitazone. *Takeda Chemical Industries, Ltd. v. Mylan Laboratories, Inc.*, 417 F.Supp.2d 341 (S.D.N.Y.2006) ("Opinion"). Pioglitazone is a highly successful drug used in the treatment of diabetes.

Takeda has now moved for an award of attorneys' fees against both defendants, arguing that this is an exceptional case. Takeda contends that each of the defendants lacked a good faith basis for its Hatch-

Waxman Act Paragraph IV certification and engaged in litigation misconduct. Takeda's motion is granted.[1]

An award of attorneys' fees should not be made without a careful consideration of the litigation as a whole and the parties' arguments. The framework established by Congress for accelerating the approval process for generic versions of established drugs, however, is not an invitation to frivolous, bad faith attacks on patents.

As described in considerable detail below, Takeda has shown by clear and convincing evidence that Alphapharm and Mylan each filed baseless Paragraph IV certifications attacking the validity of the '777 Patent. Alphapharm's certification, which asserted invalidity due to obviousness, was deeply flawed and Alphapharm revised its theory again and again in a futile effort to state a prima facie case of obviousness. Mylan completely abandoned its Paragraph IV theory of invalidity and proceeded to trial on a contorted claim that Takeda had engaged in inequitable conduct before the Patent and Trademark Office ("PTO"). Beyond their

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1. The Opinion mistakenly described Howard Rosenberg as one of Alphapharm's trial experts. Opinion at 381 n. 64. Howard Rosenberg was a fact witness for Alphapharm. Mylan served Michael Rosenberg's expert report, but before trial withdrew its proffer of him as an expert. The Opinion also erred when, in a moment of unintentional literary homage, it identified Alphapharm's expert Brian Wright, a Professor of Economics at the University of California at Berkeley, as Richard Wright. *Id.* at 345.

baseless certifications, Alphapharm and Mylan each engaged in other litigation misconduct. Their misconduct was exceptional and fully justifies the award of attorneys' fees.

Legal Standard

By operation of law, Alphapharm and Mylan each infringed Takeda's patent by filing an Abbreviated New Drug Application ("ANDA") to make a generic form of pioglitazone before the expiration of Takeda's '777 Patent. 35 U.S.C. § 271(e)(2). An ANDA announces the intention of the filer to produce a bioequivalent form of a drug already approved by the FDA. When filing the ANDA the applicant must make a certification regarding any patent protecting the drug that will be copied. Both Alphapharm and Mylan chose to make a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) ("Paragraph IV"), certifying that the patent protecting pioglitazone was invalid. In making the certification, Alphapharm and Mylan were required to give Takeda notice of the " 'factual and legal basis' of invalidity." *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed.Cir.2000) (citing to 21 U.S.C. § 355(j)(2)(B)(ii)).

An ANDA filer must "display care and regard for the strict standards of the Hatch-Waxman Act when challenging patent validity." *Id.* Such challenges are only authorized under the Hatch-Waxman Act "in accordance with strict statutory requirements" and require the challenger to state in the Paragraph IV certification that

"in the opinion of the applicant *and to the best of his knowledge,* that each patent for which the applicant is seeking approval is invalid." *Id.* (citation omitted). ANDA filers are thus held to a "duty of due care" under the Hatch-Waxman Act. *Id.*

Among the remedies that are available when a patent is infringed by the filing of an ANDA is an award of attorneys' fees under 35 U.S.C. § 285 ("Section 285"), which allows the award of attorneys' fees to the prevailing party in "exceptional cases." *Id.* at § 271(e)(4). The determination of whether a case is exceptional is made by looking at the "totality of the circumstances." *Yamanouchi,* 231 F.3d at 1347 (citation omitted). In order to justify an attorneys' fees award the evidence that the case is exceptional must be "clear and convincing." *Interspiro USA, Inc. v. Figgie Intern. Inc.,* 18 F.3d 927, 933 (Fed.Cir.1994). If a case is determined to be exceptional, the decision to grant attorneys' fees is not automatic; an award should only be made when it is separately determined that it is warranted. *Id.*

Litigation misconduct that may support an "exceptional case" finding under Section 285 includes "vexatious or unjustified litigation or frivolous filings." *Glaxo Group Ltd. v. Apotex, Inc.,* 376 F.3d 1339, 1350 (Fed.Cir.2004). For example, cases that arise from the filing of an ANDA may become exceptional for purposes of Section 285 "if the ANDA filer makes baseless certifications." *Yamanouchi,* 231 F.3d at 1347; *see also Glaxo Group,* 376 F.3d at 1351 (noting that "baseless accusations of invalidity" permit an award of attorneys'

fees against ANDA filers). A baseless certification includes the failure "to present even a prima facie case of invalidity in filing [the] paragraph IV certification." *Glaxo Group,* 376 F.3d at 1350. The Federal Circuit has cautioned, however, that "the *mere fact that a company has filed an ANDA application or certification* cannot support a finding of willful infringement for purposes of awarding attorney's fees." *Id.* at 1350-51 (emphasis supplied). Filing a baseless Paragraph IV certification and proceeding to challenge a patent's validity despite glaring weaknesses in the theory of invalidity constitute litigation misconduct. *Id.* at 1350. Where a non-prevailing party has pursued litigation in good faith, an award of attorneys' fees is only warranted where that party has engaged in misconduct in the litigation. *See Brooks Furniture Mfg., Inc. v. Dutailier Intern. Inc.,* 393 F.3d 1378, 1381 (Fed.Cir.2005); *Forest Labs., Inc. v. Abbott Labs.,* 339 F.3d 1324, 1328-29 (Fed.Cir.2003).

Takeda's motion for an award of attorneys' fees from Alphapharm will be addressed first. This ruling presumes familiarity with the Opinion, which contains the findings of fact and conclusions of law following trial and which is incorporated by reference. Nonetheless, various terms, references and findings which are set out in detail in the Opinion are on occasion also briefly described here.

Appendix B

Discussion

I. Alphapharm

A. Reliance on Advice of Counsel

Before discussing the merits of the motion addressed to Alphapharm, it is necessary to determine whether Alphapharm may oppose this motion by relying on two opinions of counsel that it first produced to Takeda on April 28, 2006, with its opposition to this motion. For several reasons, it may not.

One of the opinions Alphapharm produced is a letter/memorandum dated July 12, 2003, and signed by Allen Kipnes ("Kipnes"), an attorney with the law firm Watov and Kipnes. Frommer Lawrence & Haug LLP ("Frommer"), Alphapharm' s outside counsel, retained Kipnes at the request of Generics [UK], an Alphapharm affiliate, to prepare a legal opinion regarding the validity of the '777 Patent. Kipnes reported that he and medicinal chemist Dr. Edward Glamkowski, with whom Kipnes consulted in preparing his opinion, had concluded that Takeda's previous disclosure of the six-methyl compound, which is referred to as compound (b) in the Opinion and here, in both an earlier patent issued to Takeda and in an article in a scientific journal, rendered pioglitazone obvious. The prior art patent discussed by Kipnes is U.S. Patent No. 4,287,200 ("'200 Patent") and the scientific article is T. Sohda et al., *Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1-Methylcyclohexylmethoxy)-benzyl] thiazolidine-2,4-*

dione (ADD-3878) and its Derivatives, Chem. Pharm. Bull., 30:3580-3600 (1982) ("Sohda II"). Kipnes noted that the '200 Patent was a "broad disclosure of the claims compounds" and that Sohda II was a more specific disclosure in which compound (b) was shown to be "among a group that showed potent activity but considerable increases in body weight and fat." Kipnes took the view that based on the two disclosures, the patent examiner "should have rejected the claims of the application on prior art grounds." At trial, Alphapharm argued that the disclosure of compound (b) in these two pieces of prior art rendered pioglitazone obvious. Specifically, it asserted that the prior art identified compound (b) as a "lead" compound whose investigation would have led to the discovery of pioglitazone.

Kipnes also opined that the differences in toxicity to the liver and heart reported in Table 1 of the '777 Patent between pioglitazone and compound (b) were not surprising, and therefore were insufficient to overcome pioglitazone's prima facie obviousness. *See* Opinion at 360-62 (describing Table 1). Primarily, Kipnes questioned whether the differences between pioglitazone and the other compounds reported in Table 1 were "material" and also suggested that those reported results contradicted statements made in the '200 Patent and Sohda II.

The second opinion Alphapharm recently produced came from Frommer attorney Jeffrey Hovden ("Hovden"). Hovden indicated that, following receipt of the Kipnes opinion, a synthetic organic chemist Dr. Ali

Berkin ("Berkin"), employed by Frommer, prepared Alphapharm's Section 355 Statement under Hovden's supervision. *See* Opinion at 366-67(describing Alphapharm's Section 355 Statement).

Alphapharm was required to disclose any reliance it wished to assert in this lawsuit on advice of counsel by July 30, 2004. Because it did not disclose at that time its intent to rely on an advice of counsel defense in opposing an award of attorneys' fees to Takeda, it may not do so now.

Takeda made no secret that it would move for an award of attorneys' fees in this case. Takeda's complaint explicitly sought an award of attorneys' fees based on a finding that this case is exceptional under 35 U.S.C. § 285. On February 11, 2004, Takeda wrote to warn Alphapharm that its Paragraph IV certification, which had been filed just two weeks earlier, on January 29, 2004, appeared to have "serious omissions and errors." As explained at a conference of July 16, 2004, and as reflected in a Scheduling Order of July 20, 2004 ("July 20 Order"), the defendants' motions to bifurcate discovery and postpone their identification of and discovery concerning any advice of counsel defense were denied due to concerns regarding efficiency, expense, and prejudice.[2] Because the defendants had not yet identified with any clarity the issues as to which they

2. Alphapharm noted at the July 16 conference that it wished to preserve its right to take an interlocutory appeal from the Order, but filed no such appeal.

might interpose such a defense, they were required to identify the issues on which they intended to assert an advice of counsel defense by July 30. Following such a disclosure, Takeda could demand production of documents withheld because of an assertion of privilege and take appropriate discovery. On July 30, Alphapharm notified Takeda that it would rely on advice of counsel as to the combination use patent issues only.[3]

Alphapharm also forfeited any right to rely on the Kipnes opinion when it did not identify the document on a privilege log or otherwise in response to Takeda's June 2, 2004 request for production of documents. The request included a demand for all documents concerning any opinion or advice of counsel sought or obtained by the defendants concerning the validity of the '777 Patent. Alphapharm has not given any excuse for this omission. Such an omission is wrongful, and provides an independent basis for the suppression of the Kipnes opinion.

Essentially, Alphapharm made a unilateral decision to disregard the July 20 Order and its discovery obligations, and to grant itself a bifurcation of discovery. Alphapharm's conduct is vexatious and constitutes litigation misconduct.

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3. Alphapharm later retracted that notice, and decided not to waive the privilege even as to the combination use patents. The combination use patents are for the use of pioglitazone in combination with other therapies. *See Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F.Supp.2d. 394, 398-99 (S.D.N.Y.2004).

Of course, the very concerns about delay, expense and prejudice which underlay the decision to deny the motions for bifurcation are resurrected by Alphapharm's attempt at this late date to reopen discovery. Even now, Alphapharm has made only the most limited and piecemeal disclosure of its privileged documents. Takeda would not be required to take this limited production at face value, but would be entitled to disclosure of all relevant documents and an opportunity to depose witnesses to test the bona fides of this reliance defense.[4]

Alphapharm asserts that the Court's decision in January of this year, on the eve of trial summations, to take separate briefing on the issue of attorneys' fees following a ruling on the merits of the challenges to the '777 Patent was a decision to bifurcate discovery on the attorneys' fees issue. This argument is frivolous.[5] The

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4. For reasons it is unnecessary to describe here, the Kipnes opinion is deeply flawed and Takeda would have been to entitled to show that Alphapharm was well aware of that fact. Based on just the Kipnes opinion and Hovden declaration, Takeda asserts that it would have taken at least five additional depositions if the material had been produced as required in 2004.

5. Alphapharm's similar argument that in July 2004, the Court "carved out the § 285 issues" is entirely specious. At the July 16 conference, the Court noted that the parties had been unclear on which issues they might assert an advice of counsel defense, and therefore ordered them to give notice by July 30 of every issue on which they intended to assert the defense. In giving this ruling, the Court noted that it would need a lot more

(Cont'd)

briefing schedule for the attorneys' fees motion in 2006 did not vacate the July 2004 Order that discovery would not be bifurcated, and Alphapharm has pointed to nothing that was said during the trial that could lead to a good faith belief that discovery would be reopened. Indeed, the motion papers filed by Alphapharm's co-defendant Mylan in opposition to this motion for an award of attorneys' fees recognizes, as they must, that Mylan cannot rely on any advice of counsel it previously received but did not disclose in 2004.

The Kipnes opinion has, in any event, very little relevance to either prong of Takeda's motion. It was obtained at least nineteen months after Alphapharm made its decision to file its Paragraph IV certification. As reported by Alphapharm, that decision had been made by November 2, 2001, at the latest; it did not obtain the Kipnes opinion until July 2003.

Similarly, Alphapharm is not in a position to rely on any work done by Berkin. Berkin is a synthetic organic chemist, and Alphapharm moved at trial, successfully,

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(Cont'd)
information to make a judgment about efficiency and duplication of effort issues that would accompany any bifurcation, if the only issue to which the defense was relevant was the issue of attorneys' fees. Because the defendants never indicated that the only relevant issue was their defense to a demand for attorneys' fees, and never presented the additional information necessary to support their bifurcation motion, there was no basis to bifurcate and no bifurcation even as to attorneys' fees.

to strike the testimony of Takeda expert Dr. James Hendrickson on the ground that a synthetic organic chemist is not qualified to opine on the selection of a lead compound for further pharmacological development. *Takeda Chem. Indus. v. Mylan Labs., Inc.*, 03 Civ. 8253(DLC), 2006 WL 83366 (S.D.N.Y. Jan. 11, 2006). As described in the Opinion, demonstrating that it would be obvious to select compound (b) as a lead compound was critical to Alphapharm's argument that the '777 Patent was invalid.[6] *See* Opinion at 375-80.

In sum, Alphapharm may not interpose an advice of counsel defense on the motion for an award of attorneys' fees. Indeed, its contention that it is entitled to do so is frivolous and vexatious.

B. Alphapharm's Paragraph IV Certification

Takeda contends that Alphapharm's January 29, 2004 Section 355 Statement was devoid of merit. Even as described in the Opinion, the Statement contained clear errors as well as arguments that Alphapharm abandoned by the time of trial. Opinion at 366-67. Viewed in its totality, Alphapharm's Section 355 Statement is so devoid of merit and so completely fails to establish a prima facie case of invalidity that it must be described as "baseless." When viewed in the context

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6. Alphapharm used the same argument in its effort to exclude testimony from Takeda expert Dr. Samuel Danishefsky. *See* Opinion at 373. The Court found that he was superbly qualified to opine in the field of medicinal chemistry. *Id.*

of the totality of this litigation, the filing strongly supports an award of attorneys' fees.

Despite the obvious deficiencies of its Section 355 Statement, Alphapharm points out that its Statement satisfied all of the "technical" requirements of the Hatch-Waxman Act and that it was supported by both an outside opinion of counsel and the work of three medicinal chemists and one synthetic organic chemist, and that it allowed Takeda to investigate Alphapharm's claims fully. Alphapharm misses the point. The question is not whether the Statement complied with the technical requirements of the Hatch-Waxman Act, but whether the Statement breached the duty of due care that is imposed on ANDA filers by the Hatch-Waxman Act and is so devoid of merit as to be baseless.

This prong of Takeda's motion rests principally on four contentions regarding the Statement. They will be addressed in turn.

1. Selection of Compound (b) as a Lead Compound and Motivation To Optimize It Through Modifications

Takeda contends that Alphapharm's Section 355 Statement does not explain why one of ordinary skill in the art would identify a compound, identified in the Opinion as compound (b), from Sohda II (one of the two writings the Statement identified as prior art) as a lead

compound worthy of further investigation.[7] This contention requires some background.

Although Alphapharm's trial presentation was characterized by a constantly shifting set of arguments, Opinion at 372 n. 37, the heart of its attack on the '777 Patent relied on the single contention that prior art compound (b) was a lead compound warranting further investigation or optimization, and that the application of two, obvious chemical processes (homologation and "walking the ring") to that compound would have led to the discovery of pioglitazone. *Id.* at 372. Thus, it was incumbent upon Alphapharm to explain in its Statement what in the prior art would have led one skilled in the art to identify compound (b) as a lead compound. For the reasons explained in detail in the Opinion, the evidence at trial showed that one skilled in the art

> would certainly not have concluded that compound (b) should be chosen as a lead compound over the many other more obvious or at the very least similarly interesting choices presented by that prior art. Indeed, Sohda II teaches away from compound (b) when it specifically comments on its negative effects on body weight and brown fat.

Opinion at 377.

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7. Compound (b) from Table 1 of the '777 Patent was compound 58 in Sohda II.

Appendix B

Despite the centrality of compound (b) to Alphapharm's trial strategy, and the herculean efforts that its trial expert made to explain despite all the evidence to the contrary why Sohda II would lead one skilled in the art to identify compound (b) as a lead compound, *see id.* at 377-78, the Statement did not even make that argument.[8] The Statement focused instead on two other compounds described in Sohda II, which the Statement then misidentified, *see id.* at 36-67, as described below. As a consequence, Alphapharm's Statement did not grapple with the many impediments evident in Sohda II for choosing compound (b) as a lead compound. In this regard, it is noteworthy that Dr. Howard Rosenberg ("Rosenberg"), the head of Alphapharm's intellectual property department, a medicinal chemist, and an Alphapharm officer who assisted in formulating the Statement, admitted in his deposition that there was "nothing" to recommend compound (b) over several other compounds, and he only chose it as a lead compound "because it was similar

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8. The Statement does not identify compound (b) as a lead compound. It merely observes that compound (b) was one of several compounds related to pioglitazone that were specifically mentioned in the '200 Patent as an example of the patented formula that has shown both low toxicity and efficacy in mice. The Statement then asserts that "the specific disclosure of [compound (b)] as described in the '200 Patent and [Sohda II] render [sic] the claimed compounds of the '777 patent, including pioglitazone, obvious and therefore unpatentable." There is no explanation for why compound (b) would have stood out from all the other compounds not related to pioglitazone or, for that matter, to the other compounds related to pioglitazone.

to pioglitazone." *Id.* at 377. This is a stunning admission that Alphapharm worked backwards from pioglitazone's success to identify what it would contend was a "lead" compound, and relied exclusively on hindsight.[9]

Alphapharm contends in opposition to this motion that Rosenberg did not impermissibly rely on hindsight, but explained in his deposition that compound (b) was identified by Alphapharm as a lead compound because the data presented in Sohda II showed that it was one of seven active compounds. It also asserts that Rosenberg only received the Statement in its final form after it had been filed. But, this analysis of the compound's activity did *not* appear in the Statement either. In any event, this iteration of Alphapharm's argument is also scientifically worthless.

Sohda II identified three compounds, and not compound (b), as having the most favorable performance. As for the seven compounds with the highest efficacy scores, six of the seven, including compound (b), were identified as having problems with either toxicity or side effects. *See* Opinion at 376.

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9. Even in opposition to this motion, Alphapharm improperly depends on post-hoc reasoning. It contends that it was obvious to identify compound (b) as a lead compound since it is a homolog of a compound covered by the '777 Patent, although not a homolog of pioglitazone. Alphapharm relies on the asserted legal principle that homologs are presumed to be *prima facie* obvious. This can not explain, however, why compound (b) would have been identified by one skilled in the art as a compound worthy of further investigation.

Sohda II simply does not support the selection of compound (b) as a lead compound. Moreover, whether Rosenberg saw the finalized Statement before its filing is quite beside the point since, as he admitted in his deposition, he "formulated" the opinion of invalidity on which Alphapharm's Statement was premised.

Alphapharm's Statement is similarly deficient in its explanation of why one skilled in the art would be motivated to modify compound (b) in a way that would lead to the discovery of pioglitazone. In making the argument that one skilled in the art would have learned from Sohda II that an ethyl and methyl are "equivalent with respect to biological activity on a closely related analog of pioglitazone," the Statement misidentified the compounds as having pyridyl rings at their left moeity, while they in fact had benzene rings.[10] *Id.* at 366-67. While Alphapharm in opposition to this motion asks this Court to find that this error was due to mere sloppiness, in fact the error is more insidious. It underscores that Alphapharm was grasping at straws, and did not act with due care or in good faith.

Alphapharm points out that its expert at trial, Dr. Henry Mosberg ("Mosberg"), referred to these same two misidentified compounds—compounds 11 and 14 from Sohda II—as examples of routine methyl-ethyl

10. A benzene ring, in contrast to phenyl ring, does not have a nitrogen atom. Opinion at 382 n. 66.

substitution or homologation.[11] But, there is no discernable pattern of biological activity associated in a comparison of the many compounds listed in Sohda II as having either a methyl or ethyl substituent.[12] Nothing in the prior art suggests that substituting an ethyl for a methyl would be of any more assistance in improving a compound's toxicity or efficacy profile than using any of the other many possible substituents or than changing course entirely and adopting a different parent structure. *See* Opinion at 383. Indeed, a careful reading of Sohda II would lead one skilled in the art to conclude that homologation had no tendency to decrease unwanted side effects. *Id.* In any event, Alphapharm is mischaracterizing Mosberg's testimony. Mosberg admitted that one of ordinary skill could not use compounds 11 and 14 to predict or extrapolate the effect of homologation to a pyridyl compound. As the trial evidence made abundantly clear, the very best that Mosberg could offer was his opinion that biological activity is unpredictable and it would have been obvious to try homologation. This is a far cry from evidence that one skilled in the art would have had any reasonable basis to expect success from homologation. *Id.* at 384-85.

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11. An ethyl group, C_2H_5, differs from a methyl, CH_3, by a single CH_2 group. They are homologs since they differ from each other through the addition of a repeating group, the single CH_2 group.

12. The term substituent is used in chemistry to describe an atom or group of atoms that is substituted in place of a hydrogen atom.

Appendix B

The Statement was required at a minimum to outline the basis for choosing compound (b) as a lead compound and for modifying it in the ways proposed by Alphapharm at trial. It did not do so. The Statement was critically deficient as a result of these failures.

2. Comparison with Ciglitazone

Takeda asserts that the Statement erred when it asserted (1) that Takeda did not demonstrate that pioglitazone was surprisingly superior to another molecule-ciglitazone[13]—and (2) that the '777 Patent disclosed an entirely different activity for ciglitazone than was disclosed in the prior art. Alphapharm's Statement contrasts the toxicity of ciglitazone reported in Table 1 of the '777 Patent, where it is described as toxic, and in the prior art, where it is described as having low toxicity. The Statement then observes:

> *The Applicant of the '777 patent did not explain the contradiction between its application and its prior art disclosure.* The prior art undermined the Applicant's

13. Takeda discovered the first thiazolidinedione ("TZD") compounds in the 1970s. By the 1990s, the introduction of TZD pharmaceuticals had revolutionized the treatment of diabetes by enhancing the muscles' ability to take glucose from the bloodstream. Opinion at 347. Takeda synthesized the TZD ciglitazone in 1978, and worked many years to develop it, until it was abandoned during human clinical trials as toxic. *Id.* at 349. Thereafter, Takeda searched for a compound that was both more potent than ciglitazone and non-toxic. *Id.*

> conclusion that the data presented in Table 1 actually showed that pioglitazone had surprising or superior toxicity level.

(Emphasis supplied.) The Statement makes largely the same observation in the context of comparing the efficacy of pioglitazone and ciglitazone as presented in the '777 Patent and in the prior art.

These assertions in Alphapharm's Statement were baseless. Alphapharm's Rosenberg admitted that pioglitazone is "clearly superior" because it is non-toxic. Opinion at 385. It is also undisputed that pioglitazone is far more potent than ciglitazone. *Id.* at 358. One skilled in the art who read the '777 Patent and the prior art would have concluded that the '777 Patent demonstrated pioglitazone's superiority over ciglitazone and would not have found any contradiction in the differences in the descriptions of ciglitazone's toxicity when it is compared to different groups of compounds. In brief, ciglitazone had low toxicity when compared to other compounds analyzed at the time of Sohda II but was far more toxic than pioglitazone.

Alphapharm's concedes that it abandoned these arguments at trial, noting that it chose to focus on other concerns with Takeda's data.[14] These arguments from

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14. To the extent that Alphapharm tries to explain its abandonment of these arguments by the time restrictions imposed at trial, that excuse is entirely frivolous. There was no limitation imposed on any party in the presentation of its (Cont'd)

its Section 355 Statement were abandoned because they were unsupportable, not because Alphapharm made a tactical decision regarding which argument should be emphasized at trial.

3. Table 1's Evidence of Pioglitazone's Superiority

Takeda asserts that Alphapharm's Statement erred when it represented that Table 1 of the '777 Patent does not show the superiority of pioglitazone. As it had done in its discussion of ciglitazone, the Statement compared earlier statements in the prior art describing certain compounds as non-toxic and briefly analyzed the statistical significance levels reported by Takeda in Table 1 to conclude that the "prior art undermined the conclusion that the data presented in Table 1 of the '777 Patent actually showed that pioglitazone had surprising or superior toxicity levels." The Statement went on to point out that several of the comparison compounds had similar (and in the case of one compound superior) efficacy scores to that reported for pioglitazone in Table 1. The Statement concluded that

> The similar, or in fact superior activity of the reference compounds coupled with the lack of support of surprising results in the toxicity

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(Cont'd)

witnesses' direct testimony and none of Alphapharm's experts pressed this point. Nor did Alphapharm contend at trial that it wished to make this argument but could not because of time restrictions.

> tests supports the conclusion that *whatever credible differences may have been presented in the '777 patent were insufficient to overcome the prima facie case of obviousness.*

Alphapharm has not responded to Takeda's contention that an award of attorneys' fees is appropriate because Alphapharm's statement made a baseless claim that the '777 Patent did not show pioglitazone's superiority. At trial, Alphapharm did not reassert this analysis from its Statement, and for good reason. As already noted above, Alphapharm's Rosenberg admitted that pioglitazone was "clearly superior" to compound (b) because of the latter's toxicity. Takeda is correct that the Statement was seriously deficient in this regard as well.

4. Secondary Indicia of Non-Obviousness

Takeda asserts that the Statement is deficient because it did not address sufficiently the secondary indicia of non-obviousness, such as the commercial success of Actos®, the brand name for the compound containing pioglitazone. Alphapharm responds that it could not address secondary considerations relevant to the issue of obviousness in its Statement since none of the information relevant to those considerations was in Alphapharm's possession at the time the Statement was drafted and it required discovery of Takeda. In particular, it contends that it could not comment on the substantial commercial success of Actos® without obtaining information about the marketing of the drug,

and Takeda's profits and forecasts. The most important fact concerning non-obviousness, the significant commercial success of Actos®, was well known to Alphapharm and required no discovery. The Statement was deficient in this regard as well.

In sum, several of the deficiencies Takeda has identified in Alphapharm's Statement are so glaring that, by themselves, they defeat any assertion that the Statement gave adequate notice of the factual basis of invalidity, was drafted with due care, or presented a prima facie case for invalidity due to obviousness.[15] Considered together they highlight that Alphapharm not only abrogated the duty of due care to which ANDA filers are held but acted in bad faith in filing its Paragraph IV certification.

C. Alphapharm's Litigation Misconduct

Takeda also asserts that this is an exceptional case because Alphapharm engaged in litigation misconduct following the filing of its Section 355 Statement. It asserts first that Alphapharm largely abandoned the articulation of obviousness in its Section 355 Statement, and presented an ever-shifting collage of arguments in a futile search for a coherent theory of obviousness. Second, without any reasonable basis and in bad faith, Alphapharm attempted at trial to convert its attack on

15. This is particularly apparent because, as Alphapharm's Statement acknowledges, it had to prove its case by clear and convincing evidence. *See* Opinion at 371.

the '777 Patent into an inequitable conduct claim. Third, as already discussed, in response to this motion, Alphapharm ignored the July 20 Order and offered an untimely advice of counsel defense.

1. Alphapharm's Search for a Theory of Obviousness

Some of the highlights in the evolution of Alphapharm's obviousness argument are as follows. As already described, Alphapharm's Rosenberg used hindsight at his deposition to explain why compound (b) would have been selected as a lead compound. That deposition occurred on March 18 and March 30, 2005. Essentially, Rosenberg identified ten lead compounds that could be identified from the prior art and several categories of substituents that it would be useful to test to compare biological activity.[16] This protocol would have required the testing of hundreds of lead compounds and could not be the basis of a challenge to the '777 Patent based on obviousness.

Barry Spencer ("Spencer") was Alphapharm's 30(b)(6) witness, and testified on May 5 and 6, 2005. He presented a complex roadmap that he asserted would have led one skilled in the art to identify two compounds as lead compounds, compound (b) being one of the two.

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16. Rosenberg identified chorides, halides and CF_3 as substitutuents to test, but did not identify ethyls. Pioglitazone has an ethyl substituent at its left mocity, the end of the compound at issue here.

This was an entirely different analysis than laid out in the Statement or described by Rosenberg, who had contributed to the drafting of the Statement. Using biological activity data from Sohda II, Spencer identified thirty-six compounds of interest, and added a thirty-seventh recommended by the author of Sohda II. Purporting to use information from Sohda II about toxicity and side effects, he narrowed the list to twenty-six. Then, using a 1980 declaration from Takeda employee and co-inventor on the '777 Patent Dr. Takeshi Fujita ("Fujita") filed in connection with an earlier Takeda patent, he narrowed the list to three. Alphapharm's Statement, however, had not identified this declaration as prior art. In any event, Spencer then eliminated one of the three because the data in the prior art indicated that it had a lower efficacy index than ciglitazone.[17]

Within two months of Spencer's deposition, Alphapharm changed course again. On July 15, 2005, it served Mosberg's expert report. Mosberg identified yet new sources of prior art: two other Takeda patents, the '779 and '605 patents, and their file histories. Based on the prior art, Mosberg posited that one skilled in the art would have identified compound (b) as a lead compound. Mosberg asserted that one skilled in the art

17. Spencer had no response when confronted at his deposition with the passage in Sodha II that warned of negative side effects generated by compound (b). He simply acknowledged the passage but continued to insist that compound (b) would be one of the compounds that would have been selected for further development.

would also have engaged in two steps to alter compound (b) and create pioglitazone: homologation and then walking the ethylated compound around the pyridyl ring that lies at the left moeity of the compound. A description of these processes can be found in the Opinion at 381-85. Mosberg did not point to anything from the prior art, however, to support a reasonable belief that the homologation and ring walking would improve a compound's efficacy and toxicity profiles. As Mosberg's notes, introduced at trial, showed, all he could assert was that these processes were "obvious to try". *Id.* at 384. Even at trial, the best that he could offer was that anything can happen when one modifies a compound, so a change for the better would not be surprising. *Id.* at 385.

Then, at his deposition on September 19 and 20, 2005, Mosberg asserted that one skilled in the art would have investigated all 2-pyridyl, 3-pyridyl, and to a lesser extent 4-pyridyl compounds.[18] Pioglitazone is a 2-pyridyl compound.

At trial, Mosberg again relied on the '779 patent[19] and identified compound (b) as a lead compound. When

18. The number indicates the position at which the pyridyl ring is attached to the body of the molecule, counting from the highest atomic weight atom in the ring and moving counter-clockwise.

19. Takeda suggests that Mosberg relied on both the '779 and '605 patents at trial, but the '605 patent is not mentioned in his trial declaration. Alphapharm nonetheless repeatedly relied on the '605 patent, identifying it as one of six pieces of prior art in its opening trial memorandum.

confronted with the many problems associated with the identification of compound (b) as a lead compound based on the prior art, Mosberg turned the identification of a lead compound on its head. He asserted, without any analytical or scientific support, that one skilled in the art would have selected compound (b) for further investigation because the prior art indicated that Takeda was *not* actively pursuing it, and Takeda would have had an advantage in the development of those compounds in which it had a head start. *Id.* at 377.

Alphapharm's response to this damning recitation of its ever-evolving theory of obviousness underscores its bad faith. It excuses Spencer's testimony on the ground that he is not a medicinal chemist and testified before Alphapharm had retained Mosberg. It characterizes the differences between Spencer's analysis and Mosberg's as "slight", when they are enormous. Finally, it justifies at least some of Mosberg's innovations on the ground that they should not have been surprising to Takeda.[20]

As for the iterations of its obviousness claim presented at trial, Alphapharm does not grapple with its utter failure to show why compound (b) would be selected as a lead compound. Instead, it now contends that the identification of a lead compound is simply not a part of the obviousness analysis since (1) pioglitazone

20. In this connection, Alphapharm refers to evidence provided by Dr. Douglas Morton from The Upjohn Company, Takeda's research partner in the development of pioglitazone.

is closely related to compound (b), which was disclosed in the prior art, and (2) closely related compounds are presumed to have similar properties and are considered prima facie obvious over the prior art. With this argument, Alphapharm essentially concedes that the many contradictory justifications presented in its Section 355 Statement and by its witnesses for the selection of compound (b) as a lead compound were utterly indefensible and fatally flawed.

Instead of defending the selection of compound (b) as a lead compound whose investigation would have led to the discovery of pioglitazone, Alphapharm asserts simply that the Manual of Patent Examining Procedure ("MPEP") allows a presumption that homologs have similar properties, and then tries to explain why the data presented by Takeda in Table 1 of the '777 Patent-data which shows the superiority of pioglitazone—were insufficient to rebut the presumption. *See* U.S. Patent & Trademark Office, Manual of Patent Examining Procedure, § 2144.09 (8th ed.2001). To do this, Alphapharm makes an entirely misleading presentation.

Alphapharm's brief in opposition to this motion contains a chart with quotations from three Takeda patents that preceded the '777 Patent. The quotations refer to TZDs[21] as a class and assert that they have low toxicity. The chart presents the statements, however, as if they represent a relative assessment of compound

21. TZD's are a class of compounds developed by Takeda for treating diabetes. *See* Opinion at 347. Pioglitazone is a TZD.

(b)'s toxicity profile. As explained in the Opinion, however, the facts laid out in Table 1 are to the contrary. Compound (b) is quite toxic, a fact that underscores the unexpectedness in the discovery of pioglitazone's nontoxicity. Opinion at 385. Again, Rosenberg admitted in his deposition that pioglitazone is clearly superior to the closest prior art, and that Table 1 of the '777 Patent established that clear superiority. It was improper of Alphapharm to continue to contest that issue after Rosenberg's deposition, and it is doubly wrongful for it to make that misleading argument at this late stage.

In any event, Alphapharm's legal analysis is flat wrong. The law requires Alphapharm to show that the prior art gave a reason or motivation to make the claimed composition. Opinion at 371 (citing *Yamanouchi*, 231 F.3d at 1343). As an initial matter, one must identify a lead compound that one skilled in the art would be motivated to modify. Alphapharm was never able to defend its identification of compound (b) as a lead compound. Moreover, the MPEP itself cautions against equating homology with prima facie obviousness. MPEP at § 2144.09.

Alphapharm similarly misrepresents Mosberg's testimony about the expectations that one skilled in the art would reasonably have from applying the processes of homologation and ring walking to compound (b). Relying on quotations from Mosberg's expert report and trial declaration,[22] Alphapharm contends in opposition

22. The trial witnesses presented their direct testimony through affidavits or declarations. Opinion at 344.

to this motion that Mosberg opined that a skilled artisan would have had a reasonable expectation of successfully obtaining a better drug albeit not necessarily a blockbuster drug. First, no one but Alphapharm has suggested that the relevant test is an expectation of a discovery of a blockbuster drug. Second, Alphapharm has simply ignored Mosberg's many concessions in his writings, and deposition and trial testimony that entirely eviscerate the formulations in his report and declaration. These include his acknowledgment that the biological effects of various substituents are unpredictable and that improvements in efficacy and toxicity profiles from homologation and ring walking were neither expected nor unexpected. Opinion at 384-85 and n. 74. By summation, Alphapharm's counsel could do little to cabin the damage done by Mosberg's trial testimony, and argued simply that an improvement in a compound's profile would not be surprising. *Id.* at 385. That, of course, falls far short of evidence of a reasonable expectation of success.

Alphapharm had over two years between the time it decided to file a Paragraph IV certification and its filing of its Statement. The assertion of obviousness in a Section 355 Statement must be rooted in an analysis of prior art and made with due care. Alphapharm was still searching for a viable theory at trial. It has utterly failed to explain why its Statement was so flawed and why its description of obviousness went through such a dramatic evolution between the filing of the Statement and trial. The evidence of Alphapharm's bad faith is overwhelming.

2. Alphapharm's Assertions of Inequitable Conduct

At trial, Alphapharm asserted several arguments of little relevance to its claim of obviousness. They are best understood as assertions that Takeda engaged in inequitable conduct. Because Alphapharm had not pleaded an inequitable conduct claim, Alphapharm's attempts to insert these new issues created confusion, wasted valuable court time, and increased the burden of the litigation on the parties.

First, in its proposed findings of fact, Alphapharm contended that Takeda presented unreliable data on toxicity to the PTO in the prosecution of the '777 Patent. It then moved to preclude Takeda's toxicology expert from explaining that Alphapharm's assertion was misleading and false. Alphapharm's assertion that the data on toxicity presented to the PTO by Takeda in the '777 Patent could not be replicated and was unreliable rested on test results that only became available *five years* after the '777 Patent was issued. *Takeda Chem. Indus. v. Mylan Labs., Inc.*, 03 Civ. 8253(DLC), 2006 WL 137374, *3 (S.D.N.Y. Jan. 11, 2006). This argument was entirely frivolous.

Then, at trial Alphapharm appeared to be fashioning an inequitable conduct argument through a comparison of the toxicity data Takeda provided to the PTO for the '777 Patent, and general statements in a prior Takeda patent application about toxicity levels found in TZDs. The comparison was spurious. Opinion at 379 n. 58.

Finally, in summation, Alphapharm added yet another new argument. The argument focused on the requirement that a patent contain a description (also called a specification) of the claimed invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112. As Alphapharm has had to concede, however, it did not choose to challenge the '777 Patent based on the adequacy of the specification and this argument was a red herring. The sole challenge brought by Alphapharm was whether the '777 Patent was obvious over the prior art and on this question its legal argument was not as persuasive as Mosberg's own handwritten notes agreeing with Danishefsky's view that based on the prior art, the impact of even small changes in a chemical compound on biological activity was unpredictable. Opinion at 384.

In sum, Alphapharm's arguments that Takeda engaged in inequitable conduct were entirely frivolous. The arguments cannot be excused as mere comment of the credibility of Takeda's witnesses, an argument that Alphapharm makes in opposition to this motion. What Alphapharm's inequitable conduct arguments underscore is that it had lost all confidence in its claim of obviousness, and was grasping at straws. This conduct further supports the award of attorneys' fees.

D. Totality of Circumstances

Alphapharm contends that in deciding whether this is an exceptional case warranting the award of attorneys' fees, the Court should weigh the closeness of the case, the conduct of the parties,[23] and the tactics of all counsel. Weighing these factors does not assist Alphapharm.

This case was not close. Alphapharm's evidence fell woefully short of demonstrating a credible claim of obviousness. The claim of obviousness was asserted without due care and prosecuted in bad faith. As already demonstrated, Alphapharm's conduct of the litigation and tactics were deeply flawed.

Alphapharm identifies a few specific factors to weigh in its favor. It contends that Mosberg's reliance on the '605 and '779 patents as relevant prior art, references which were not disclosed in its Section 355 Statement, was an appropriate response to Takeda's contention that Sohda II taught away from compound (b) as a lead compound. The fact that Sohda II taught away from compound (b), however, was not news.[24] The Statement

23. Alphapharm has raised only one claim that Takeda engaged in misconduct in defending the '777 Patent. In a footnote, Alphapharm faults Takeda for raising issues concerning the '902 patent for the first time at trial.

24. Sohda II identified three compounds, none of which was compound (b), as exhibiting the most favorable properties in terms of activity and toxicity. It warned that compound (b) caused considerable increases in body weight and brown fat. Opinion at 375-76.

did not even identify compound (b) as a compound of interest disclosed in Sohda II. To the extent that the '605 and '779 patents provided any support for the selection of compound (b) as a lead compound, then Alphapharm was under an obligation to identify these two references in its Statement.

Alphapharm contends that it "took steps at every juncture to simplify the issues" for trial, pointing to its consent to the severance of the trial of the claims associated with the combination use patents, its completion of fact discovery during the time allowed, its withdrawal of its jury demand, its reduced request for time to present its case at trial,[25] and its use of only two experts. Alphapharm has not shown, however, that these decisions were anything other than decisions taken in its own interest and/or decisions as to which it had no viable alternative. In any event, they are insufficient when weighed against the other evidence of misconduct described in this Opinion to prevent an award of attorneys' fees.

Alphapharm also asserts that attorneys' fees should not be awarded because it relied upon a well respected and experienced medicinal chemist, Mosberg. Actually, Alphapharm did not rely on Mosberg's analysis until the time of the trial. Mosberg had no role in the formulation of the Statement or in the presentations made by Rosenberg and Spencer. Mosberg's analysis of

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25. Alphapharm notes that it reduced its request to two days, which the Court further reduced to eight hours.

obviousness was eviscerated at his deposition and trial. Indeed, in opposing this motion, Alphapharm does not rely on Mosberg's explanation of why compound (b) would have been seen by one skilled in the art as a lead compound, relying instead on Rosenberg's analysis, which was also thoroughly discredited at trial. As for the second prong of Mosberg's testimony, his explanation as to why one skilled in the art would have been motivated to apply homologation and ring walking to compound (b) in order to optimize the molecule, during summation Alphapharm's counsel struggled to limit the damage done by Mosberg's testimony on these issues as well. *See* Opinion at 385.

In contrast to the defendants, Takeda brought to the trial scientists of extraordinary accomplishment and distinction who took the time they needed to study the issues thoroughly and to develop their analyses. *See* Opinion at 373 n. 39. While Mosberg is certainly a respected and experienced medicinal chemist, for whatever reason he did not devote the care and attention to this assignment that it deserved. As a result, he delivered a series of opinions that were completely undercut by a careful examination of the prior art and the application of sound science. Alphapharm must bear the responsibility for this and cannot avoid the imposition of sanctions by hiding behind Mosberg's resume.

In sum, Takeda is entitled to an award of attorneys' fees from Alphapharm. Alphapharm's Section 355 Statement was deeply flawed, filed in bad faith, and fails

to present even a prima facie case of invalidity. Alphapharma made these proceedings far more complex and expensive by constantly shifting its theory of obviousness in a futile effort to locate a coherent argument. Even in response to this motion, it has misrepresented the record in this litigation. This is the exceptional case where an examination of the totality of the circumstances amply justifies, indeed compels, the award of attorneys' fees.

II. Mylan

Takeda has moved for as award of attorneys' fees against Mylan for filing a Paragraph IV certification in bad faith and for litigation misconduct following the close of fact discovery. Mylan abandoned in its entirety its claim of obviousness contained in its Section 355 Statement, and then after the close of discovery propounded a frivolous claim of inequitable conduct. These, and the other grounds pressed in Takeda's motion, are detailed below.

A. Mylan's Obviousness Claim

Mylan filed a Paragraph IV certification in bad faith and with no reasonable basis to claim that the '777 Patent was invalid. Its Section 355 Statement was deeply flawed and never defended during discovery. Mylan then engaged in further misconduct, attempting to substitute a new theory of obviousness following the close of fact discovery. The Court rejected Mylan's attempt to alter its theory of obviousness at that late stage. Mylan's

misconduct was exceptional and deserves the imposition of sanctions.

Mylan decided to challenge the validity of the '777 Patent without any good faith basis to do so. The relevant facts are as follows. Even though it had not yet obtained an opinion to support a Paragraph IV certification, Mylan stationed a person outside the FDA office on May 27, 2003, over six weeks prior to July 15, the first day it could file an ANDA, intending to have a "line stander" hold its place on a 24/7 basis.[26] Mylan had retained the law firm of Foley Hoag, LLP as of April 2003 to analyze the '777 Patent, but the firm was unable to provide an opinion of invalidity by July 15. With July 15 swiftly approaching, on July 11, Mylan hired Levy & Grandinetti, a two person law firm, to prepare an opinion, and the firm did so after just sixteen hours of work. Mylan did not produce that opinion during the course of this litigation. With the opinion in hand, it made its ANDA filing on July 15, and then returned to Foley Hoag, which completed its work in August. Foley Hoag was not responsible for preparing Mylan's Section 355 Statement, however, and its August opinion was not produced in this litigation either. Instead, Mylan retained its trial counsel, Cohen, Pontani, Lieberman & Pavane, to prepare its Statement, which was filed on September 8, 2003. Within five weeks, on October 13, Takeda warned Mylan that its certification lacked merit and was an abuse of the statute and the rules.

26. The FDA demanded that Mylan's line stander leave the premises.

Appendix B

Mylan's Section 355 Statement identified two pieces of prior art, the '200 Patent and Sohda II. It argued that one compound with a benzene ring at its left moeity made the invention of pioglitazone obvious. (The pioglitazone molecule had a pyridyl ring, not a benzene ring, at its left-moiety.) Mylan misdescribed the benzene compound's structural relationship to pioglitazone and its efficacy as disclosed in Sohda II. Opinion at 367-68. It also gave no reason to select the compound as a lead compound warranting further investigation and optimization.

Mylan resisted discovery of its theory of obviousness, and then when again ordered by the Court after the close of fact discovery to do so, it gave notice that it had abandoned the theory of obviousness set forth in the Statement. *See Takeda Chem. Indus. v. Mylan Labs., Inc.*, 03 Civ. 8253(DLC), 2005 WL 2092920, *1 (S.D.N.Y. Aug. 31, 2005); *Takeda Chem. Indus. v. Mylan Labs., Inc.*, 03 Civ. 8253(DLC) (S.D.N.Y. entered on June 21, 2005) (Memorandum Opinion and Order limiting Mylan's presentation of evidence at trial to theories set forth in September 8, 2003 Notice). In its stead, Mylan sought to substitute a new theory of obviousness based on a different compound mentioned in Sohda II. The Mylan Statement had focused on compound 14; Mylan's new theory focused on compound 57 (which was described at trial as compound 3894, a compound that had an unsubstituted pyridyl ring as its left moeity). Mylan did not give any detailed explanation of why compound 57 would have been identified by one skilled in the art as a lead compound, or how its

optimization would have led to the discovery of pioglitazone. This theory was also advanced in bad faith: Mylan's 30(b)(6) witness had just days earlier indicated that an analysis of the toxicity and efficacy profile of compound 57 would have ruled it out as a lead compound.

In an Order entered on June 21, 2005, Takeda's motion to preclude Mylan from asserting this revised theory of obviousness was granted. Mylan then moved for reconsideration, inappropriately raising several new arguments and making legal arguments that were absolutely frivolous. *Takeda Chem. Indus. v. Mylan Labs., Inc.*, 2005 WL 2092920, *4. The motion for reconsideration was denied on August 31, 2005. *Id.* at *6.

Mylan's defense to this prong of the motion for sanctions is entirely unpersuasive. Mylan asserts that it did not need a good faith basis to have a line-stander, and argues that Takeda is drawing an impermissible negative inference regarding the advice Mylan received from counsel even though Mylan has elected to rely on its right to withhold the opinions as privileged. *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344-45 (Fed.Cir.2004) (en banc).

Mylan also asserts that it is not required to obtain advice from outside counsel so long as it has another basis for a *bona fide* belief that the '777 Patent was invalid. Mylan asserts that it relied on its in-house patent attorney Shelly Monteleone, who customarily

consults with both outside counsel and Mylan scientists before deciding whether an ANDA could be filed. The problem with its assertion of reliance on Monteleone, however, is that she testified that she had no recollection of actually doing any work on the pioglitazone project and could only testify as to her customary practices.

An adverse inference may not be drawn against Mylan for its failure to present an opinion from counsel that could establish its *bona fides* in filing an ANDA and then its Statement. Without relying on any such inference, however, Takeda has carried its burden of showing that Mylan did not act with due care or in good faith.

As for the substance of its Section 355 Statement, Mylan asserts that it should not be judged against the standard of success at trial, that is, whether it had clear and convincing evidence of obviousness, but rather whether it had "a reasonable basis" for asserting that one skilled in the art "would be interested in compound 14." Mylan relies on its characterization of compound 14 and pioglitazone as "non-classical bioisosteres", and a purported presumption that compounds that are so related have broadly similar biological properties, automatically rendering pioglitazone obvious in Mylan's view. Mylan points out that, in any event, it dropped the claim, and the mere fact that it had pleaded it does not constitute vexatious litigation.

This defense of the merits of its Section 355 Statement is utterly frivolous, and is further evidence

that an award of attorneys' fees against Mylan is appropriate. Sohda II described 101 specific TZD compounds, giving data on each compound's efficacy. Opinion at 350-53. Mylan has never presented any explanation for why one skilled in the art would single out compound 14 in Sohda II as a lead compound warranting further investigation. Mylan's 30(b)(6) witness could not identify any basis to differentiate the compound from the many others that the article described as performing better or as well as it did. Moreover, Mylan has never presented any expert testimony to support its theory that the compound is a bioisostere of pioglitazone. In contrast, Takeda's distinguished expert explained in his expert report that it is not. In any event, neither Mylan's Section 355 Statement, nor its opposition to this motion, present any explanation of why one skilled in the art would have been motivated to make the substantial modifications to compound 14, which has a benzene moeity, to arrive at pioglitazone, which has a pyridyl moeity at its left end.

Finally, Mylan attributes its delay in identifying its second theory of obviousness on Takeda's delay in producing an unredacted version of internal Takeda report A-15-34. *See* Opinion at 357-58. According to Mylan, the document disclosed that compound 57 (a/k/a compound 3894) had comparable activity and "only slightly greater toxicity" than pioglitazone. It points out that Takeda was not burdened by Mylan's assertion of this revised theory of obviousness since the Court precluded Mylan from asserting it at trial. Mylan contends that its motion for reconsideration was justified

since the Court had overlooked the issue of prejudice as articulated in *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed.Cir.1998). As was explained in the decision denying Mylan's motion for reconsideration, *Lydall* does not require a finding that Takeda had been prejudiced to preclude Mylan's last-ditch obviousness theory, but even if it were necessary to find prejudice, there was ample evidence that Takeda had been prejudiced. *Takeda Chem. Indus. v. Mylan Labs., Inc.*, 2005 WL 2092920, *5-6.

Mylan's defense of its aborted effort to make a wholesale revision to its obviousness theory is utterly frivolous. As this Court has previously had occasion to point out to Mylan, *Takeda Chem. Indus. v. Mylan Labs., Inc.*, 2005 WL 2092920, at *4, since an attack based on obviousness must rely on disclosures made in prior art, the existence or receipt of Takeda's internal documents is irrelevant. Either the invention of pioglitazone was obvious based on prior art, or it was not. It is also extremely misleading of Mylan to characterize compound 3894 as having only slightly greater toxicity than pioglitazone. Compound 3894 was disqualified by Takeda and Upjohn from further consideration in the Fall of 1984 because of its toxicity to the heart. Opinion at 397. Toxicity was of paramount concern to the two companies as they selected the handful of compounds into which they would be investing considerable resources. *Id.* at 358-59. In contrast to compound 3894, pioglitazone met the companies' toxicity criteria. *Id.* at 359.

In sum, Mylan's ANDA filing and Statement were baseless and filed in bad faith. On this ground alone, Takeda would be entitled to an award of attorneys' fees.

B. Mylan's Litigation Misconduct Associated with Pursuit of an Inequitable Conduct Claim

Takeda also moves for an award of attorneys' fees on the grounds that Mylan (1) did not have a good faith basis for its inequitable misconduct claim; (2) wrongfully delayed disclosing the claim in order to prejudice Takeda; (3) was unable to identify any material misstatement in Takeda's application for the '777 Patent; (4) relied on Dr. Lawrence Hendry ("Hendry") as an expert for issues on which he was not qualified to opine, *see Takeda Chem. Indus. v. Mylan Labs., Inc.*, 03 Civ. 8253(DLC), 2006 WL 44053 (S.D.N.Y. Jan. 9, 2006) (granting in part Takeda's *motion in limine*); (5) frivolously asserted that Takeda had suppressed evidence that pioglitazone was toxic to the liver; (6) asserted that compound 3894 was the closest prior art when it knew it was not; and (7) lacked any theory or evidence of Takeda's intent to mislead the PTO. Mylan responds to only some of these issues. It presents no defense directed specifically to items 4, 5 and 6.

Before analyzing these issues, a brief description of Mylan's claim of inequitable conduct is in order. Mylan's theory of inequitable conduct was cobbled together from arguments addressed principally to two compounds, one of whose test results were reported by Takeda on Table 1 of the '777 Patent, and one whose results were

not. Opinion at 390. Mylan argued that Takeda misrepresented the data regarding compound (c)'s potency in order to make it appear that the compound was weaker than pioglitazone. There were a host of problems with this theory, including the fact that Takeda had evidence that compound (c) had failed the chick lens assay test and had therefore been categorically eliminated as a candidate for development because of its toxicity. *Id.* at n. 82. Therefore, whatever its efficacy, pioglitazone could easily be shown as superior to compound (c). With respect to compound 3894, whose test results Takeda did not present to the PTO, Mylan argued that it was the closest prior art to pioglitazone, and that Takeda had a duty to disclose its performance in tests to the PTO. This theory was also fatally flawed for many separate reasons, including the fact that compound 3894 was not the closest prior art, that Takeda had no duty to present the PTO with information about the compound, and that in any event it had been rejected for development by Takeda due to its toxicity to the heart.

Proof of wrongful intent is of course a necessary component of an inequitable conduct claim. *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1128 (Fed.Cir.2006); Opinion at 387-88. Mylan never had any evidence of wrongful intent by Takeda, and despite promises at trial that it would produce some, utterly failed to do so. In contrast, there was powerful, irrefutable evidence that Takeda acted with complete integrity in its dealings with the PTO. Opinion at 389-90, 398-99. Among other things, when it made its

application to the PTO it presented the very test results upon which it and Upjohn had relied internally in making their joint selection of the compounds into which they would invest further research resources to try to develop a pharmaceutical. *Id.* at 389, 398.

As for Mylan's delay in asserting this claim, Mylan waited until the end of the period for fact discovery to request leave to amend its answer and counterclaims to assert invalidity based on inequitable conduct. Despite Mylan's tactical maneuvers, designed to hamstring Takeda's ability to confront this new theory, the Court granted Mylan's request. The Court explained that it was doing so because of the public interest in having issues decided on the merits, and not based on a finding either that Mylan had acted with sufficient diligence or that it had a good faith basis for its claim.

Mylan argues that the Court must have found "good cause" for Mylan's amendment of its pleadings to add the inequitable conduct claim since the Court applied that Rule 16, Fed.R.Civ.P., standard when granting the motion to amend. Mylan asserts that it was delayed in bringing its claim of inequitable conduct by Takeda's failure to complete document production until February 4, 2005, and Mylan's need to translate Japanese documents. It points out that its claim rested in large part on the assertion that back-up for test results listed in Takeda's internal reports and presented to the PTO could not be located in Takeda laboratory notebooks. *See* Opinion at 390. Mylan asserts that it notified the Court and Takeda through a letter of March 15, 2005,

that Takeda may have procured its patent through inequitable conduct.

Mylan further contends that its assertion of inequitable conduct based on compound 3894 was not frivolous because Takeda did not advise the PTO that both pioglitazone and compound 3894 were both five times more potent than ciglitazone despite internal reports indicating that to be true. Further, it argues that since the data indicated that compound 3894's heart toxicity was "at the lowest level used by Takeda to indicate toxicity," the materiality of the omission of a discussion of the compound in the application for the patent was a "close question." Mylan points out that the Opinion containing the judgment of this Court following trial discussed these issues over the course of several pages, which must indicate that the issues were "worthy of serious consideration."

As the Court explained to the parties at the time, its decision to allow Mylan to bring its claim of inequitable conduct was absolutely not a finding that it was timely or meritorious. Nor can the February production of documents justify the assertion of the claim, since the claim was always frivolous. Mylan's assertions about compound 3894 were particularly egregious, and its continued defense of that assertion in this motion practice is inexcusable. Mylan's expert Hendry admitted at trial that compound 3894 was not the closest prior art to pioglitazone, and by the time of summations Mylan had abandoned any claim that it was. Opinion at 397 n. 104. At trial, Mylan scrambled to try

to avoid the evidence that the compound was cardiotoxic by, for example, suggesting that further testing and further statistical analysis of the test results were necessary to confirm the toxicity. Mylan did neither, however. Takeda did the additional statistical analysis and reconfirmed the reliability of the finding. *Id.* at 397-98 and nn. 103 & 104.

Mylan does not and cannot point to any passage in the Opinion of February 21, 2006 that suggests that any of its arguments were meritorious. While Takeda conceded that it had made two errors in describing the protocol for its testing to the PTO, neither of those errors was material, neither would have come close to supporting a finding of inequitable conduct, and Mylan does not suggest anything to the contrary in opposing this motion. The Opinion's length was driven in large part by the defendants' presentation of so many different arguments and iterations of those arguments. To place the findings of fact in context it was necessary to explain the history of the discovery of pioglitazone and the science relevant to the many issues raised by the defendants' claims. The length of neither that Opinion nor this can be fairly read as evidence that the defendants' claims had any merit. They did not.

Mylan contends that it had reason to question Fujita's credibility since Takeda was unable to produce laboratory notebooks to confirm all of the experimental data reported in Takeda's internal reports. As was noted above, Fujita led the research effort that resulted in the discovery of the pioglitazone molecule and was named

as co-inventor on the '777 Patent. Fujita, who had been long retired from Takeda by the time of this litigation, did not undertake the search for the notebooks during the discovery period and opined that the contemporaneous internal Takeda reports that he authored were reliable and that if notebooks could not be found for some of the results, then some of the notebooks must be missing. *See* Opinion at 390. There is absolutely no basis to argue, much less find, that Fujita was ever anything but honest.

Mylan asserts that Takeda's motive to mislead the PTO can be found in the admission by an Upjohn witness that patentability was something you are always concerned about, and Mylan's speculation that Takeda did not want to disclose compound 3894 to the PTO because it was well-known in the prior art and not patentable, and yet "comparable to pioglitazone in activity and toxicity." Mylan was not even aware of the existence of this Upjohn witness at the time it moved to amend and plead its inequitable conduct claim. In any event, the Upjohn witness testified at trial that patentability was not a driving consideration since Takeda and Upjohn were focused first and foremost on identifying a compound that was effective with extremely low toxicity. As just explained, Mylan's assertion that compound 3894 was comparable to pioglitazone is absolutely false and misleading. It could not establish that proposition at trial, and the repetition of the assertion in this motion practice further warrants the award of sanctions.

Takeda has shown that in each of the seven ways it has identified Mylan acted without a reasonable basis and in bad faith in pursuit of its inequitable conduct claim. For these reasons, Takeda is entitled to attorneys' fees for the period following the close of fact discovery.

C. Mylan's Other Litigation Misconduct

Takeda also moves for sanctions because other misconduct by Mylan increased the expense and burden of the litigation. It asserts that Mylan (1) disobeyed court orders setting the schedule for depositions and requiring Mylan to produce a 30(b)(6) witness to respond fully to a deposition notice; (2) on the eve of trial tried to revisit earlier discovery rulings; (3) improperly tried to supplement its inequitable conduct theory on the eve of trial and prevent Takeda from responding to the attempt; (4) made an untimely motion for reconsideration regarding a ruling on a motion in limine concerning Hendry, then purported to withdraw it, only to reverse course again in an attempt to reassert the motion.

Mylan does not address the first issue. It asserts that Takeda suffered no prejudice from Mylan's eve of trial efforts, as set out in items 2 and 3, since the Court rebuffed them. As to the fourth item, it asserts that it fully withdrew the motion for reconsideration, and Takeda was never burdened with the necessity of responding to it in writing.

By themselves, these actions would not support a finding that this is an exceptional case that warrants an award of attorneys' fees. When taken together with the remainder of Mylan's misconduct, however, Takeda has shown that in each instance these actions constitute litigation misconduct and supply additional support for the award.

D. Mylan's Remaining Arguments in Opposition

None of Mylan's arguments in opposition to this motion are persuasive or alter the conclusion that the totality of Mylan's conduct in this litigation justifies an award of attorneys' fees. Mylan's opposition to this motion rests principally on policy arguments. It contends that Congress intended to foster ANDA patent litigation when it enacted the Hatch Waxman Act, that twenty-two of the thirty ANDA litigations that yielded a court decision have been decided in favor of the ANDA applicants, and that in nine of those cases the patent was ruled invalid.

There is no basis to find that this award of fees will deter ANDA filings and litigation. This award addresses baseless ANDA filings and the pursuit of frivolous ANDA litigation in bad faith and other litigation misconduct. The Hatch-Waxman Act cannot be read to immunize such conduct.

Mylan also requests a stay of a decision on this motion pending a ruling by the Federal Circuit on the appeal from the judgment entered at the conclusion of

the trial and/or the completion of the litigation on the combination use patents. Mylan's previous request for a stay was denied, and will not be reconsidered here.

Mylan contends that a decision on the motion should not be made because the Court needs to weigh the amount of attorneys' fees being sought, and Takeda has not yet presented a request for a specific award. The amount of any award will be decided after Takeda has submitted its request for a specific amount and the parties are given a full opportunity to be heard as to the size of any award.

Mylan asserts that Takeda's motion should be denied because Takeda (1) moved for an award of attorneys' fees against Mylan in its pre-trial memorandum of law dated November 18, 2005 on the ground that Mylan had filed a baseless Paragraph IV certification, when *Glaxo,* 376 F.3d at 1351, bars an award when the filing is the sole basis for the motion; and (2) served a bill of costs on April 11, 2006, although a notice of appeal had already been filed and costs cannot be taxed during the pendency of an appeal. As for Takeda's November 18 motion, it did not seek sanctions based on the filing of the certification, but on the grounds both that the certification was baseless and that Mylan had committed "myriad acts of litigation misconduct." Takeda did not catalogue the misconduct in its pretrial memorandum, but has done so now. As for the bill of costs, Takeda explains that it filed it within the time required by the local rule.

Appendix B

Mylan argues that no fees that Takeda incurred before June 6, 2005 should be awarded against it since that is the first date of misconduct alleged by Takeda against Mylan. June 6 is the date Mylan served its supplemental interrogatory responses and asserted for the first time that the '777 Patent was invalid for obviousness on the basis of the prior disclosure of compound 3894. Because Mylan had filed its certification in bad faith, and thereafter participated in the litigation over the validity of the '777 Patent on a frivolous claim of obviousness, it was in a position to move to amend its pleading and assert the claim of inequitable conduct. These actions were inextricably intertwined, and the application to limit the award to the period following June 6, 2005 is denied.

Alphapharm and Mylan point to the remarks of the Court at the conclusion of the trial in which the Court thanked the parties for their hard work and level of preparation. The comments accurately reflect the hard work that each party put into the actual presentation of the evidence during trial, but said nothing about the merits of the parties' legal positions. Those positions were described in the Opinion and here. For the reasons set forth herein, Mylan's case is exceptional and an award of attorneys' fees against Mylan as well as Alphapharm is entirely justified.

Conclusion

Takeda's motions for an award of attorneys' fees is granted as to both Mylan and Alphapharm.

SO ORDERED.

Dated: New York, New York

September 20, 2006

DENISE COTE

United States District Judge

APPENDIX C — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK FILED MARCH 21, 2007

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

03 CIV. 8253 (DLC), 04 CIV. 1966 (DLC)

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

-v-

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., and UDL LABORATORIES, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

-v-

ALPHAPHARM PTY. LTD. and GENPHARM, INC.,

Defendants.

Appendix C

March 21, 2007, Decided
March 21, 2007, Filed

OPINION & ORDER

DENISE COTE, District Judge:

This Opinion addresses the size of the fee award which will be made in favor of plaintiff and patentee Takeda Pharmaceutical Company, Ltd. and its affiliate Takeda Pharmaceuticals North America, Inc. (collectively, "Takeda") against two generic drug companies: Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively, "Mylan"); and Alphapharm Pty. Ltd. and Genpharm, Inc. (collectively, "Alphapharm"). Due to the defendants' exceptional misconduct and bad faith, Takeda is awarded $11,400,000 from Mylan and $5,400,000 from Alphapharm with interest accruing from September 20, 2006 at a rate of 5.02%.

BACKGROUND

On March 10, 2006, judgment following a non-jury trial was entered in favor of Takeda and against Mylan and Alphapharm. The two generic drug companies had challenged Takeda's U.S. Patent No. 4,687,777 ("'777 Patent"), which protects the invention of the chemical compound known as pioglitazone, which is used in the treatment of diabetes. *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 417 F.Supp.2d 341 (S.D.N.Y.2006) ("Trial Opinion"). As reflected in the Trial Opinion and

in the decision awarding attorney fees to Takeda for exceptional misconduct by Alphapharm and Mylan, *see Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 459 F.Supp.2d 227 (S.D.N.Y.2006) ("Sanctions Opinion"), Alphapharm and Mylan each filed baseless Paragraph IV certifications under the Hatch-Waxman Act and engaged in litigation misconduct. *Id.* at 231. Alphapharm's certification, which asserted invalidity due to obviousness, "was deeply flawed and Alphapharm revised its theory again and again in a futile effort to state a prima facie case of obviousness." *Id.* Mylan abandoned its Paragraph IV theory of invalidity and at the close of discovery substituted an inequitable conduct claim. *Id.* at 249. This claim was "fatally flawed for many separate reasons." *Id.* at 248. Familiarity with the Trial and Sanctions Opinions is assumed.

After the issuance of the Sanctions Opinion, the parties litigated the amount of the award. On November 20, 2006, Takeda moved for an award of fees of $14,052,873,[1] with $9,633,149 due from Mylan and $4,419,724 due from Alphapharm.[2] It sought an

1. Takeda argues that the minimal award should be approximately $12.3 million. To arrive at this figure, it applied its hourly rates as of January 2005, the *midpoint* in the litigation, to the total hours subject to the award. The requested figure of over $14 million is derived from the application of the 2006 hourly rates of the plaintiff's law firm to all of the work on which this request is made.

2. Takeda also presents another set of figures. It asserts that, based on its current rates, it is entitled to $9,429,025 from Mylan and $4,356,011 from Alphapharm.

enhancement of this award to reflect the particularly egregious misconduct in this case and due to the fact that the New York City market rates of intellectual property litigators are 37 to 44% higher than those charged by plaintiff's counsel. Takeda calculated that it was owed $1,661,938.70 in disbursements (of which $1,107,959.13 is allocated to Mylan and $553,979.57 to Alphapharm), and an additional award of $1,003,443.25 to cover its expert disbursements, which it contends should be awarded through this Court's inherent power as an additional appropriate sanction given the nature of the misconduct in this litigation. Takeda seeks interest from September 20, 2006, the date of the Sanctions Opinion, at a rate of 5.02%, which it derives from 28 U.S.C. § 1961.

Takeda has identified tasks that it completed which related solely to Mylan or Alphapharm and those which related to both defendants. Takeda proposes that two-thirds of the joint time be allocated to Mylan and one-third to Alphapharm. It proposes this division because Mylan acted as lead defense counsel with respect to discovery of the obviousness claims,[3] and then added considerably to the complexity of the case with its untimely assertion of an inequitable conduct claim. This allocation is consistent with the complexity of the issues litigated at the trial, where the Court allocated the trial time between the defendants in the same way.

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3. Mylan will enjoy a six-month exclusivity period if the '777 Patent is invalidated. Trial Opinion, 417 F.Supp.2d at 365.

Mylan contends that Takeda is entitled to no more than $2 million in fees and expenses from Mylan, given the many problems that it asserts infect Takeda's billing records. Alternatively, it calculates the joint fees as approximately $7.3 million, which should be reduced to approximately $4.2 million and divided evenly between Mylan and Alphapharm. As for the fees attributable to Mylan alone, Mylan calculates those to be nearly $4.7 million, which should be reduced by 25% to yield approximately $3.5 million and further reduced by $1 million to reflect errors. It calculates that together these joint and Mylan-specific fees amount to an award against Mylan of just over $4.6 million.[4]

Alphapharm asserts that it owes Takeda between $1.38 and $1.57 million in fees. To arrive at this figure, it subtracts hours to which it objects for one reason or another, subtracts another 30% for what it asserts is excessive billing, and then applies either the hourly rate from a survey of 2004 billing rates or the 2005 rates for plaintiff's law firm.

Following its consideration of the arguments made by Mylan and Alphapharm, Takeda revised its request modestly (and not always downwardly). It now seeks attorney fees of $9,640,636 against Mylan and $4,470,397 against Alphapharm, each to be enhanced by 37 to 44%; disbursements of $1,080,504 against Mylan and $553,980 against Alphapharm; expert fees of $668,962 against

4. Mylan does not adequately explain how it arrived at this figure or even an approximation of this figure.

Mylan and $334,481 against Alphapharm; and interest at a rate of 5.02 from September 20, 2006, the date of the decision awarding fees.

DISCUSSION

The award of attorney fees in patent infringement litigation is authorized by 35 U.S.C. § 285 ("Section 285"), which provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." In determining "reasonable" attorney fees, a court may use what is known as a hybrid lodestar approach. This approach begins with the calculation of the "lodestar" amount, an initial estimate of reasonable attorney fees calculated by multiplying the number of hours reasonably expended on the litigation times a reasonable hourly rate for attorneys and paralegals. *City of Burlington v. Dague*, 505 U.S. 557, 559 (1992); *Blanchard v. Bergeron*, 489 U.S. 87, 94 (1989). While there is a "strong presumption" that the lodestar is reasonable, *City of Burlington*, 505 U.S. at 562 (citation omitted), district courts may "adjust [the] lodestar calculation by other factors." *Blanchard*, 489 U.S. at 94. "[T]he most critical factor" in determining the reasonableness of a fee award "is the degree of success obtained." *Farrar v. Hobby*, 506 U.S. 103, 114 (1992) (citation omitted). Consideration may also be given to the experience, reputation and ability of the attorneys as well as to the difficulty of the issues presented and the amount at stake in the litigation. *Hensley v. Eckerhart*, 461 U.S. 424, 429-30 n. 3 (1983) (citing the twelve factors listed in *Johnson v. Georgia Highway*

Express, Inc., 488 F.2d 714, 717-19 (5th Cir.1974)). A request for attorney fees "should not result in a second litigation," although the district court should provide a "concise but clear explanation of its reasons for the fee award." *Hensley*, 461 U.S. at 437.

To aid a court's calculation of the lodestar, the prevailing party must provide contemporaneous time records, affidavits, and other materials to support its application for the amount of reasonable hours expended. *McDonald v. Pension Plan of the NYSA-ILA Pension Trust Fund*, 450 F.3d 91, 96 (2d Cir.2006); *see also PPG Indus., Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1570 (Fed.Cir.1988) ("insufficient documentation may warrant a reduction in the fees"). A reasonable hourly rate for attorney fees is a rate that is "in line with those [rates] prevailing in the community for similar services by lawyers of reasonably comparable skill, experience and reputation." *Blum v. Stenson*, 465 U.S. 886, 896 & n. 11 (1984). The community that a district court should consider to determine the lodestar figure "is normally the district in which the court sits." *Reiter v. MTA New York City Transit Auth.*, 457 F.3d 224, 232 (2d Cir.2006) (citation omitted); *see also New York State Assoc. for Retarded Children, Inc. v. Carey*, 711 F.2d 1136, 1140 (2d Cir.1983). In determining a reasonable rate, a court may refer to American Intellectual Property Law Association ("AIPLA") surveys. *See Mathis v. Spears*, 857 F.2d 749, 755 (Fed.Cir.1988).

Alphapharm contends that Federal Circuit law-not Second Circuit law-applies to the determination of reasonable attorney fees under Section 285 and cites for support *Special Devices, Inc. v. OEA, Inc.*, 269 F.3d 1340, 1343 (Fed.Cir.2001) ("[T]he awarding of attorney fees pursuant to 35 U.S.C. § 285 is an issue unique to patent law therefore [is] subject to Federal Circuit law.").[5] *See also Serio-US Indus., Inc. v. Plastic Recovery Techs. Corp.*, 459 F.3d 1311, 1321 (Fed.Cir.2006) ("This court applies Federal Circuit law to the issue of attorney fees in patent infringement cases."). Neither *Special Devices* nor *Serio-US Indus.* considered the method for calculating the amount of an attorney fee award.[6] In any event, Alphapharm has not pointed to any inconsistency between Federal and Second Circuit law in the standards that are applied to calculate attorney fees. The Federal and Second Circuits both emphasize that the calculation of a reasonable attorney fee may begin with the lodestar figure and relies upon the district court's exercise of discretion to increase or decrease that figure in light of other factors. *See View*

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5. Takeda aptly points out that Alphapharm's counsel has taken a contrary position on its website, which opines that "[t]he law of the regional circuit is applied to determine a reasonable attorney's fee award."

6. *Special Devices* considered the issue of whether an unquantified award of attorney fees is immediately appealable. *Special Devices*, 269 F.3d at 1343. *Serio-US Indus.* concerned whether the district court adequately supported its determination that the case was "exceptional" and merited an award of attorney fees. *Serio-US Indus.*, 459 F.3d at 1322.

Eng'g, Inc. v. Robotic Vision Sys., Inc., 208 F.3d 981, 988 (Fed.Cir.2000) (upholding district court's reduction of lodestar after consideration of relevant factors to reach final sanction award); *Orchano v. Advanced Recovery, Inc.*, 107 F.3d 94, 98 (2d Cir.1997) (citing *Hensley*, 461 U.S. at 434) (district court may adjust lodestar upward or downward after due consideration of other factors, including the "degree of success obtained").

The Federal Circuit has emphasized that a reasonable attorney fee is "a determination that lies primarily within the discretion of the district court," which may "consider all the relevant circumstances in a particular case." *Junker v. Eddings*, 396 F.3d 1359, 1365-66 (Fed.Cir.2005).

> [T]rial judges enjoy discretion to award attorney fees for good reason. After presiding over the preparation and trial of the case, the trial judge can best weigh the relevant considerations, such as the closeness of the case, the tactics of counsel, the flagrant or good faith character of the parties' conduct, and any other factors contributing to imposition of punitive sanctions or to fair allocation of the burdens of the litigation.

Perricone, M.D. v. Medicis Pharm. Corp., 432 F.3d 1368, 1380-81 (Fed.Cir.2005) (citation omitted); *see also Hensley*, 461 U.S. at 437 (district court's exercise of discretion to determine fee award is warranted by its

superior understanding of the litigation and the "desirability of avoiding frequent appellate review of what essentially are factual matters."). Thus, the

> district court's inherent equitable power and informed discretion remain available in determining the level of exceptionality rising out of the offender's particular conduct, and in then determining, in light of that conduct, the compensatory quantum of the award, including the amount of attorney fees, what if any expenses shall be included, and the rate of prejudgment interest, if any, on the award.

Mathis, 857 F.2d at 754.

A. Takeda is Entitled to a Substantial Fee Award.

Takeda seeks to recover at a minimum approximately $14 million in attorney fees through this application. This sum is entirely reasonable and amply supported by the records it has submitted with its request. This Court has supervised this litigation from its inception and is intimately familiar with the work done by all counsel, the challenges presented in defending against the defendants' shifting attacks on the '777 Patent, the intensity with which these two lawsuits were fought, and the complexity of the evidentiary and scientific problems posed by the litigation.

A lodestar calculation by Takeda in the vicinity of approximately $20 million would not have been

surprising. The defense of an extraordinarily profitable pharmaceutical was at stake here, a drug that had contributed to a revolution in the treatment of a serious and widespread disease. The work done by Takeda's counsel was uniformly excellent. Its written submissions were reliable; it made factual statements that were rooted in the record; and it presented legal arguments that reflected a thorough understanding of the relevant law and were well researched. In the many pretrial conferences held during the course of discovery and in preparation for the trial, its counsel was always well-prepared, courteous and knowledgeable. Managing discovery in this litigation, which included an enormous production of decades-old Japanese documents, was extraordinarily demanding. Takeda's lawyers responded effectively and swiftly to a stream of attacks on the patent, attacks which kept shifting right up to the time of trial summations. These attacks drew from different scientific disciplines; some were based on the molecular structure of the compounds Takeda investigated; others focused more on the scientific method Takeda employed in its selection of pioglitazone for development.

The quality of Takeda's trial presentation is particularly notable. Complex scientific materials were presented in an entirely accessible manner. Volumes of documents were organized and synthesized. The briefs, affidavits constituting witnesses' direct testimony, and proposed findings included citations that provided quick access to the trial record. None of this could have happened without a dedicated effort by a well-

coordinated team. In sum, Takeda was well represented in this litigation and this Court was greatly assisted by the fine work done by Takeda's counsel.

Mylan and Alphapharm contend that the fee request is unreasonable. They assert that attorney fees have been awarded in only two Abbreviated New Drug Application ("ANDA") cases, and that in neither did the award exceed $2 million. *See Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 51 F.Supp.2d 302, 309 (S.D.N.Y.1999) (granting $1,635,440 in attorney fees); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 264 F.Supp.2d 753, 784 (S.D.N.Y.2003) (granting $1,523,580.85 in attorney fees). Reviewing all awards in patent cases under Section 285 since 2000, Mylan asserts that no fee award has exceeded $5.2 million. Alphapharm located two awards far surpassing that amount. The court in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95 Civ. 8833(RPP), 2002 WL 1733681, at *16 (S.D.N.Y. July 26, 2002), after intensive litigation over the validity of a pharmaceutical patent, awarded almost $27 million in attorney fees and disbursements under Section 285 and, over defendants' objection, also awarded sanctions of almost $6 million for expert fees and pre-judgment interest.[7] Over a decade ago in *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, No. H-89-3203, 1993 WL 268680, at *5-6 (S.D.Tex. Feb. 17, 1993), the court awarded attorney fees of almost

7. The defendants also objected to the payment of computer research fees. *Bristol-Myers*, 2002 WL 1733681, at *14.

$18 million and costs of over $235,000 pursuant to Section 285 following a jury trial.

It is unnecessary to examine the awards made in other cases. This Court is well familiar with the record in this case, the quality of work performed here, the degree of success achieved by Takeda, and the general cost of complex litigation in New York City. An award of attorney fees of approximately $14 million is entirely justified, and for the reasons described below, even a significantly larger award than the lodestar amount would be justified.

B. Size of Staff

None of the specific attacks which the defendants have made on the size of the fee request here has merit. Mylan contends that Takeda's counsel overstaffed the case and spent too much money to defend a single patent.[8] Mylan asserts that this reflects a lack of judgment. In a similar vein, Alphapharm complains that Takeda is seeking reimbursement for the work of 72 separate persons.

While it is true that over the course of this roughly three-year litigation Takeda's counsel used many professionals, an examination of the distribution of the

8. Alphapharm makes precisely the opposite point. It contends that the amount of the fee request is excessive because Takeda's sales exceed $2 billion a year, in effect arguing that Takeda can afford the expense of litigation.

work reflects a well-organized team effort.[9] Two partners devoted approximately three thousand hours each to this effort, with two other partners working just over 1,000 hours on the matter.[10] Two counsel worked on the matter: one for just over 1,000 hours and one for less than 500 hours. Three associates each worked over 3,000 hours; three others worked less than 2,000 hours apiece; and eight others worked less than 1,000 hours apiece. Only one contract attorney worked more than two thousand hours, while two others each worked over 1,000 hours, and fourteen worked more than 200 hours. Thus, the bulk of the work was appropriately concentrated in the hands of a team of professionals with different levels of experience and expertise. An examination of the billing records does not reflect overstaffing.

Mylan asserts that too many professionals attended the same meetings or court appearances, and that Takeda should not be reimbursed for the duplicative

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9. The discussion in the text ignores the hours billed by a professional when those hours amounted to less than 200 hours over the course of the case. Two partners and one counsel worked less than 100 hours; many associates worked less than 200 hours. This pattern is consistent with what would be expected in major litigation: personnel are pulled in to help with a discrete task or when the demands of meeting a particular deadline require it.

10. One of the partners acted as the senior partner on the matter; two others divided the bulk of the trial work between them.

use of personnel. Alphapharm makes the same point, citing attendance at three meetings in particular. This argument is without merit. It would be impossible to run litigation of this magnitude without multiple attorneys attending some of the same meetings and court appearances. The defendants have not succeeded in pointing to any abuse in this regard by Takeda's counsel.

To the extent that Mylan questions the number of Takeda professionals who attended the trial, that objection can also be swiftly rejected. Takeda had no more professionals attending the trial than did the defendants. In addition, because the Court took direct testimony by affidavit and was thoroughly familiar with that testimony, the trial exhibits, and the parties' arguments before the trial began, and because the trial days were devoted exclusively to the cross-examination and re-direct examination of witnesses and summations, the trial was conducted in a relatively brief time-frame when measured against the complexity of the evidentiary and legal issues. The careful preparation and efficient presentation by trial counsel permitted the trial to move ahead apace, without unnecessary delay. There was no overstaffing at trial.

C. Survey Comparisons

Relying on an AIPLA survey (the "Survey"), Alphapharm contends that Takeda's request is too high since the average total cost for patent infringement litigation in New York City is just over $6 million. The

Survey, which was conducted in 2005, received thirty-five responses from attorneys practicing in the New York City CMSA.[11] They reported that in the typical patent infringement litigation with no unusual complications in which over $25 million was at stake, the average cost of the litigation in 2004 was just over $6 million, with one-quarter of the cases exceeding $8 million.

Takeda attacks the reliability of the Survey, noting among other things that too few respondents provided information to make its results reliable.[12] *See Yurman Designs, Inc. v. PAJ, Inc.*, 125 F.Supp.2d 54, 57 (S.D.N.Y.2000) (rejecting AIPLA survey of hourly rates for a New York City intellectual property attorney because fewer than ten percent of attorneys surveyed responded to the inquiry). It is unnecessary to resolve the parties' dispute as to the reliability of the Survey since the Survey's results actually confirm the reasonableness of the Takeda fee request.

Although only one patent was at stake here, the profitability of the patent for Takeda, and the incentive that those profit figures provided to the defendants,

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11. It is not clear how much of the area that surrounds New York City was included in what the Survey labels as the New York City CMSA.

12. The Survey does not indicate its return rate, but does note that usable questionnaires were received from 1,558 individuals. Only 299 of that number answered the question at issue here, and *only 35* of the 299 came from the "NYC CMSA".

meant that the litigation over the validity of the '777 Patent was enormously important to all parties. Moreover, because Mylan altered course in mid-stream, abandoning its theory of obviousness and opting instead to pursue a theory of inequitable conduct, the litigation was equivalent to two atypical and massive patent cases.[13] Compared to "average" litigation with something over $25 million at stake, this case was unusual litigation, with billions of dollars at stake. Incurring costs that triple or quadruple the cost of the "average" case reflected in the Survey would be entirely unsurprising.

D. Mylan's Experts

Mylan has reserved the bulk of its attack on the fee request for the opinions offered by two purported experts. Takeda has moved to strike the declarations from James H. Wallace, Jr. ("Wallace") and John J. Marquess ("Marquess").

Marquess, the President of Legal Cost Control, Inc., identifies himself as a fee auditor. With just nine days of work, he contends that he conducted a meaningful audit of millions of dollars in billings by Takeda's counsel. Notably, Mylan did not request Marquess to provide any opinions regarding "the substantive nature or

13. Mylan itself has estimated that an ANDA filer would anticipate spending between $5 and $12 million to litigate a single ANDA case. It is interesting that neither Mylan nor Alphapharm has offered evidence of their own attorney fees in this litigation as a point of comparison with Takeda's fee request.

quality" of the professional services. Instead, Marquess represents that he reviewed "each" billing line item and considered it in light of "reasonable billing practices within the legal and professional community," or what he terms "generally accepted legal and professional billing practices."

A few examples from his report suggest the quality of his work. His procedures include "unblocking" entries in which a single time charge lists multiple activities. To unblock the entry, he divides the time through a pro-rata allocation to each activity without making any distinction based on the complexity of the activity or how the time was or would likely have been spent on a single task. As another example, he questions the general practice among law firms of using contract attorneys and contends that a law firm may not properly charge its client a "mark up" on the cost of employing such attorneys.

Mylan has not shown that Marquess' opinion qualifies as admissible expert evidence. Marquess has no experience in patent law or complex litigation. He has no familiarity with the substance of the Takeda litigation, and made no effort to become familiar with it. His work purports to apply generally accepted billing practices, but Mylan has failed to show that there is any such standard, or that Marquess has followed *any* recognized standard in preparing his evaluation of the Takeda fee request. Thus, the Marquess report is rejected to the extent it is offered as an expert opinion. *See In re Worldwide Direct, Inc.*, 316 B.R. 637, 642-43

(D.Del.2004) (rejecting Marquess, whose opinion was offered under the name of his firm, as an expert fee auditor).[14]

Even if the Marquess opinion were admissible as an expert opinion, it is singularly unhelpful. Because of his lack of experience in complex litigation much less patent litigation, his opinion about the reasonableness of the fee request here is entitled to essentially no weight. Moreover, his method of reviewing the time charges is deeply flawed. For instance, he has identified no reasonable standard that would suggest it is appropriate to apportion time equally among several tasks performed during a block of time without consideration of the nature of the tasks. He criticizes the use of contract attorneys without any analysis of the types of tasks they performed in this case and whether their use in fact resulted in efficiencies for Takeda. In complex litigation, contract attorneys are routinely used by well-established law firms who supervise their work. Mylan has failed to show that it was inappropriate for Takeda's counsel either to use contract professionals in this case or to use them to the extent that it did.[15]

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14. Remarkably, Marquess did not report that the court in *Worldwide* had rejected him as an expert. Although he and Mylan try to excuse the omission, their failure to disclose the *Worldwide* court's rejection of his opinion as admissible expert evidence was a breach of their duties to the court.

15. It is interesting to note that Mylan has not proffered that it was able to litigate this case without the use of contract professionals.

Appendix C

Mylan asks that Marquess' opinion at least be accepted as summary evidence. To the extent that summary figures from the Marquess report are also contained in Mylan's brief, they have been considered in connection with Mylan's arguments on this application.

Wallace, the second proffered expert, is a partner at Wiley Rein & Fielding LLP.[16] He represents that he has "handled" patent litigation, including ANDA trials for Mylan during the last eleven years. After reviewing the Sanctions Opinion and Takeda's briefs and affidavits in support of its November 2006 fee application, he opines that Takeda's request is "grossly excessive." As a point of comparison, he describes the fees his law firm incurred in two patent cases: a 2005 case in which he represented Mylan, including at a nine-day trial;[17]

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16. Wallace has charged Mylan $595 per hour, which he describes as his "normal rate." This disclosure of Wallace's "normal" fee is additional evidence that Alphapharm's objections to the hourly rates charged by Takeda's lawyers is utterly baseless. Wallace has provided surprisingly little information about himself or his firm, but it does not appear that he is based in New York City. It appears that he bases his practice in Washington, D.C.; he is not admitted to practice in either the Southern or Eastern District of New York, and although he is admitted to practice before many Courts of Appeals, he is not admitted to practice before the Court of Appeals for the Second Circuit.

17. Mylan's attacks on the adequacy of the Takeda submission in support of the fee request stand in stark contrast (Cont'd)

and a 2001 through 2003 case litigating a non-pharmaceutical patent. His other point of comparison is his survey of ANDA and non-ANDA cases since 2000.

Wallace's opinion is inadmissible since he has failed to conduct an adequate investigation of this litigation so that he could render a helpful opinion. *See Brooks v. Outboard Marine Corp.*, 234 F.3d 89, 92 (2d Cir.2000). He did not examine the Trial Opinion, the time records submitted by Takeda that describe in detail the work its attorneys performed on this matter, or otherwise do the work which would have given him a reasonable basis to evaluate the fee request and compare it to the cost of any other litigation with which he is familiar.

Even if it were admissible, Wallace's opinion would be entitled to no weight given the inadequacy of his investigation of the Takeda matter. Moreover, his points of comparison show that his opinion is utterly unreliable. In the 2005 litigation which he handled for Mylan, Wallace pointed out to that court that a generic company challenging a patent in ANDA litigation would ordinarily incur "far less" in attorney fees than the patentee. Despite the existence of this obvious and relevant point of reference, Wallace pointedly does *not* offer Mylan's

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(Cont'd)
to the positions it took in the 2005 case in which it was represented by Wallace. In that case, Mylan submitted billing records which indicated only the monthly charge for "professional fees" without any detail from which to determine which attorneys had worked on the matter, their hourly rate, their hours or the tasks they performed.

attorney fees in the Takeda matter as a point of comparison. Moreover, his "survey" of Section 285 fee awards omits reference to the award of over $32.6 million in *Bristol-Myers* in 2002. Sadly, it would appear that Wallace has let his relationship with Mylan interfere with his obligation to provide an opinion based on careful and considered analysis.[18]

E. Allocation Between Mylan and Alphapharm

Mylan challenges the allocation of fees and costs proposed by Takeda. In preparation for this fee request, Takeda's counsel reviewed all of its contemporaneous time entries to allocate the time among work performed directly on issues presented by Mylan, by Alphapharm or by both defendants. As explained above, it has allocated two-thirds of the joint time to Mylan.[19] Mylan

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18. Since Mylan did not give notice of its intent to rely on expert testimony, Takeda has been deprived of an opportunity to take discovery of the experts. Since neither expert has provided opinion testimony that is helpful to the Court, it is unnecessary to delay a ruling on Takeda's application to give it an opportunity to take such discovery.

19. As the first ANDA filer, Alphapharm was entitled to enter the market six months in advance of any generic drug competitor. *See* Trial Opinion, 417 F.Supp.2d at 365. Alphapharm lost that advantage to Mylan by January 2004, when the Food and Drug Administration found that Alphapharm was unable to make a bioequivalent to the patented drug. *Id.* & n. 27. Plaintiff's counsel originally recorded all of their time defending the '777 Patent under a single matter assigned to Mylan. In December 2005, it created separate matter numbers for Mylan and Alphapharm.

contends that it was inappropriate for Takeda's counsel to rely on an after-the-fact allocation of tasks to separate those performed because of the litigation with Mylan from those associated with the Alphapharm litigation. Takeda's procedures for reviewing its contemporaneously entered billing records to make an appropriate allocation between Alphapharm and Mylan were perfectly reasonable and acceptable.

Mylan proposes that the "joint" time be evenly divided between the parties or disallowed, but has little or no reasoned response to Takeda's argument that it should pay for two-thirds of the joint time. Takeda's suggestion for the unequal division of the cost of the joint work is adopted. Mylan added very significantly to the expense, burden and complexity of the litigation. It is only fair to Alphapharm to require Mylan to bear more than half of the expense associated with the "joint" tasks. If the positions Mylan took during the litigation had been meritorious, this analysis might be different. As explained in the Trial and Sanctions Opinions, however, Mylan's litigation strategies were adopted in bad faith.

F. Contemporaneity and Block Billing

To support its fee request, Takeda submitted over 500 pages of spreadsheets containing over 8,000 contemporaneous time entries.[20] The entries list a

20. The defendants' assertion that Takeda's counsel has not produced contemporaneous time records is flat wrong.

timekeeper, the hours spent, and a narrative description of the task performed.

Mylan argues that some of the time entries represent improper "block" billing. Alphapharm asserts that 158 billing records reflect work of more than 15 hours in a single day. When these entries are examined with an understanding of the billing practices used by Takeda's law firm, there is nothing misleading or inappropriate about them. The defendants' attacks are rejected.

Finally, Alphapharm asserts that the bills are not sufficiently detailed to support a review for reasonableness. It is wrong. In the Court's experience, the records its counsel maintained reflect the standard practices of major law firms, in particular in the level of detail they record. In the current business environment for the legal profession, law firms must be prepared to respond to clients' detailed inquiries about their bills. The records that support this fee request would provide ample scope for a detailed review by the client, and more than adequate scope for review by the court that has overseen the litigation.

G. Clerical Work and Miscellaneous Matters

Alphapharm and Mylan complain that Takeda used attorneys to perform purely clerical tasks. While it is important that attorneys delegate tasks that can be performed by less highly compensated personnel, it is unrealistic to expect that all of the work that might be

described as "clerical," for example preparing and organizing materials for discovery and trial, can be delegated. In a complex case, such work requires a coordinated effort by a team of professionals that includes attorneys and paralegals. For example, no competent trial lawyer will allow exhibits to be prepared and organized for witnesses and the Court without the attorneys who will be responsible for presenting the evidence in the courtroom directly supervising that effort. Alphapharm, whose own attorneys have sought reimbursement in other patent litigation for virtually identical work, has not shown that Takeda's fee request is unreasonable in this regard.

Alphapharm also contends that work by library and administrative personnel is purely clerical and cannot be recovered. Takeda has shown that these individuals have billed time to this litigation when they were conducting research or other tasks specific to this case. The time is properly compensable.

The Court has reviewed each of the defendants' arguments about other specific items in the Takeda fee request. Each of them is rejected whether or not specifically addressed in this Opinion. In some instances, Takeda has made adjustments. In others, the defendants' complaints rely on a misrepresentation of the documentation. In others, the complaints are not well-founded for entirely separate reasons. The objections related to the amount of time spent conducting legal research on the issue of personal jurisdiction, on the preparation of and response to

discovery requests, and on editing two privilege logs,[21] are specifically denied. Finally, Alphapharm and Mylan contend that the time spent preparing an animation for use at trial can only be recouped as a cost pursuant to 28 U.S.C. § 1920, and not as attorney fees. When attorneys, as opposed to outside vendors, work on such a project, their time is properly recoverable pursuant to Section 285.[22]

H. Hourly Rates

As already noted, the community in which the litigation is conducted provides the baseline for determining a reasonable hourly rate for attorney fees, and a court may draw upon "its knowledge of the relevant market when determining the reasonable hourly rate." *McDonald*, 450 F.3d at 96-97. Moreover, a district court should use "current rather than historic hourly rates," *Reiter*, 457 F .3d at 232 (citation omitted), in setting the hourly rate for the lodestar calculation.

Takeda has calculated a lodestar figure using its September 2006 rates for its law firm's professionals, rather than their hourly rates at the time they performed the work. It has also calculated a lodestar based on the rates that existed as of January 2005,

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21. The logs were over 200 pages long and contained close to 4,000 entries.

22. Alphapharm's own counsel has sought to recover its fees for similar work in other litigation.

roughly the midpoint of the litigation, as an alternative, more conservative measure. Takeda contends, however, that the award should be enhanced in either case because its counsel's fees were lower than the prevailing rates of intellectual property litigators in New York City.

Two sets of rates illustrate Takeda's point. The 2006 rates for the partners who worked on this matter ranged from $375 to $600, with an average of $498. Those rates for associates ranged from $175 to $385, with an average of $278. The average rates for the partners who worked on Takeda's litigation were over 20% lower than the effective rates of intellectual property litigators in New York City in 2004 and 2005, as reported by the PricewaterhouseCoopers LLP 2005 and 2006 Billing Rate & Associate Salary Surveys ("PWC Surveys"). The spread was larger for the associates working on Takeda's litigation. *See also Yurman,* 125 F.Supp.2d at 55, 58 (finding $520 hourly rate for a New York City copyright and trademark litigation partner to be reasonable in 1999).

Alphapharm contends that the 2006 rates for the partners who worked on the Takeda matter are higher that the average billing rate for intellectual property partners in New York City, as reflected in the AIPLA survey for 2004. It admits that the rates for associates who worked on the Takeda matter are lower than those in the survey, but contends that it is significant that Takeda did not submit affidavits for the associates reporting on their level of experience and skill. These and similar arguments are unconvincing. Alphapharm

does not deny that the PWC Surveys are far more reliable than the AIPLA survey since they contain more detailed information that is specific to New York City and the timeframe for our litigation.

Alphapharm urges that the 2005 and not the 2006 billing rates should be used in any event since most of the litigation occurred in 2005, and the rates of plaintiff's law firm were affected by its merger in November 2005 with another law firm. The 2006 rates are more appropriate. There is no requirement that a court apply historic rates, and the 2006 rates are entirely reasonable when judged against the relevant community standard.

I. Enhancement

Mylan opposes any enhancement to Takeda's lodestar recovery. It asserts that the lodestar figure is recognized under the law as reasonable, and that an enhancement is only warranted when there is either excessive delay in payment or public policy support for it.

Takeda would certainly be fairly entitled to an enhancement of about $3 million, with $2 million charged to Mylan and $1 million charged to Alphapharm. It would reflect Takeda's degree of success, which was complete on each and every one of the many points in contention, and the defendants' outrageous litigation conduct, which amply justifies sanctions beyond the out-of-pocket cost of this litigation to Takeda.

What is truly exceptional here is the cascade of attacks each defendant made on the '777 Patent. If the defendants had simply pursued the theories presented in their Paragraph IV certifications, the cost of litigation would have been far lower and a simple award of the lodestar calculation may have been warranted. They did not rest there, though. In each instance the Section 355 Statement was so lacking in merit that it was entirely abandoned by the time of trial. The parties increased the cost and burden of this litigation enormously through their shifting theories of attack, none of which was meritorious or adopted in good faith. None of the theories reflected a careful analysis of the relevant documents and the application of sound science to that analysis. Alphapharm's extensive list of asserted and then abandoned obviousness theories is summarized in the Sanctions Opinion. Sanctions Opinion, 459 F.Supp.2d at 240-41. Mylan resisted discovery on the theory of obviousness contained in its Section 355 Statement, and then after the close of discovery sought to substitute another frivolous theory of obviousness. It also asserted an inequitable misconduct claim that was thoroughly discredited at trial. *Id.* at 246-50.

The award of attorney fees to Takeda without an enhancement already compensates it, of course, for the extra expense incurred in responding to this litany of meritless theories and the associated misconduct. More would be entirely appropriate, however, to reflect the extensiveness of the misconduct here, in particular its repetitive nature. A wildly successful pharmaceutical patent will of course draw attacks. There is a strong

public interest, as acknowledged by the statutory scheme, in challenging patents that keep the price of patented pharmaceuticals high. There should be no incentive, however, for litigation that is prolonged and complicated by a series of attacks undertaken without a good faith basis and without a sound basis in science. Science, medical research, and the court system demand better. Because Takeda's expert fees are also being awarded, however, an enhancement to the lodestar amount will not be separately entered.

J. Expenses

Takeda has requested over $1.6 million in reimbursable expenses under 35 U.S.C. § 285. Alphapharm contends that Takeda cannot recover expenses beyond those identified in 28 U.S.C. §§ 1821 and 1920.[23] The bill of costs submitted here amounts to

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23. 28 U.S.C. § 1821 provides for witness fees. It states in pertinent part

> (a)(1) Except as otherwise provided by law, a witness in attendance at any court of the United States, or before a United States Magistrate Judge, or before any person authorized to take his deposition pursuant to any rule or order of a court of the United States, shall be paid the fees and allowances provided by this section . . . . (b) A witness shall be paid an attendance fee of $40 per day for each day's attendance. A witness shall also be paid the attendance fee for the time necessarily occupied in going to and returning from the place of

(Cont'd)

$229,568.81, all of which is for items not included in the Section 285 request.

(Cont'd)

attendance at the beginning and end of such attendance or at any time during such attendance.

28 U.S.C. § 1920 enumerates costs associated with litigation.

Taxation of costs

A judge or clerk of any court of the United States may tax as costs the following:

(1) Fees of the clerk and marshal;

(2) Fees of the court reporter for all or any part of the stenographic transcript necessarily obtained for use in the case;

(3) Fees and disbursements for printing and witnesses;

(4) Fees for exemplification and copies of papers necessarily obtained for use in the case;

(5) Docket fees under section 1923 of this title;

(6) Compensation of court appointed experts, compensation of interpreters, and salaries, fees, expenses, and costs of special interpretation services under section 1828 of this title.

A bill of costs shall be filed in the case and, upon allowance, included in the judgment or decree.

Alphapharm's statement of the law is incorrect. The Federal Circuit has interpreted the term "attorney fees" under Section 285 "to include those sums that the prevailing party incurs in the preparation for and performance of legal services related to the suit." *Mathis*, 857 F.2d at 757 (citation omitted). As an exception to the American Rule that each party bears its own attorney fees and expenses, Section 285 was expressly added by Congress to provide attorney fees and expenses in "exceptional cases." This provision is intended

> to discourage conduct which fell within the scope of "exceptional," by requiring the party acting exceptionally to bear the expenses of the opposing party. It would be inconsistent with the intent of § 285 to limit the prevailing party to something less.

Central Soya Co., Inc. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1578 (Fed.Cir.1983) (citation omitted). With this understanding, the Federal Circuit has upheld district courts' discretionary grant of expenses to prevailing parties under Section 285 beyond expenses enumerated in Sections 1821 and 1920. *Id.* (upholding district court's discretionary grant of expenses under Section 285); *Mathis*, 857 F.2d at 758 (finding that "it would be inconsistent with the intent of Section 285 to limit prevailing-party Hydro to something less than the fees and expenses to which it was subjected by Mathis in this 'very exceptional' case of 'gross injustice' " and that "28 U.S.C. §§ 1920 and 1821 are not here applicable.").

Mylan asserts that the expenses should be allocated equally and the amount reduced dramatically. Both defendants contend that the award of expenses should be denied because Takeda did not provide invoices to document its disbursements. Takeda supported its request for reimbursement of disbursements with a computer printout of the contemporaneous billing entries for the disbursements. This documentation is sufficient.

As far as the individual items which Mylan contends are not reimbursable expenses, its contention is rejected. It has not identified one item that is not a customary and appropriate expense associated with litigating a complex patent case, or indeed, any complex litigation. As Takeda points out, Mylan's counsel has sought reimbursement for these very kinds of expenses in other patent litigation.

K. Expert Fees

Takeda admits that its expert witness fees cannot be awarded under Section 285 as ordinary litigation expenses. *See Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 23 F.3d 374, 377 (Fed.Cir.1994). It seeks reimbursement of these fees under this Court's inherent power to impose sanctions for bad faith and vexatious conduct. *Chambers v. Nasco, Inc.*, 501 U.S. 32, 46 (1991). "[I]f in the informed discretion of the court," neither the applicable statute nor the Federal Rules of Civil Procedure sanctioning bad-faith litigation conduct "are up to the task, the court may safely rely on its inherent

power." *Id.* at 50. Specifically, a district court, "in the exercise of its discretion and inherent equity power," may "include an award of reasonable expert witness fees in excess of the $30/day attendance fee specified in 28 U.S.C. § 1821." *Mathis,* 857 F.2d at 759. *See also Amsted,* 23 F.3d at 378; *Bristol-Myers Squibb,* 2002 WL 1733681, at *14.

Takeda's request is granted. For the reasons already described in detail in a prior Opinion, "[t]he evidence of Alphapharm's bad faith is overwhelming." Sanctions Opinion, 459 F.Supp.2d at 243. Similarly, Mylan engaged in a host of bad faith litigation tactics, which increased the burden of this litigation enormously. These included the presentation of factually indefensible positions from its ANDA filing straight through to its submissions in opposition to the motion for sanctions. *Id.* at 247-48.

An award of the costs associated with Takeda's employment of experts is particularly warranted in this case. To analyze fairly and correctly the challenges that the defendants made to the '777 Patent, it was necessary for the Court to understand the principles and issues associated with several scientific disciplines. Takeda brought to this task experts of impeccable credentials who spent the time that they needed to master the facts relevant to the challenges to the patent so that they could present the relevant scientific principles and their expert opinions in an accessible and helpful manner. Their testimony was critical to the findings of fact entered in the Trial Opinion.

Appendix C

Takeda's approach to the use of experts stood in stark contrast to that of the defendants. As a general matter, the defendants' experts were far less impressive, had not done their homework regarding the issues at stake in this case, and often ventured from their fields of expertise. The defendants' performance in this regard provides further evidence that they well understood that their attacks on the '777 Patent were groundless and would only succeed if Takeda did not expend the effort and resources necessary to shine a light on the flaws in the defendants' arguments and if the Court did not spend the time necessary to learn the relevant science and understand the evidentiary record created by the trial submissions.

L. Interest

Takeda seeks an award of interest on the attorney fee award from the date the Sanctions Opinion was issued: September 20, 2006. It contends that such an award is appropriate under Section 285, or alternatively, as an exercise of the Court's inherent equitable power as a sanction for bad faith conduct.

According to 28 U.S.C. § 1961, "[i]nterest shall be allowed on any money judgment in a civil case recovered in a district court. . . . Such interest shall be calculated from the date of the entry of the judgment, at a rate equal to the weekly average 1-year constant maturity Treasury yield." Post-judgment interest is correctly calculated "from the date of the judgment establishing the right to the award." *Fox Indus., Inc. v. Structural*

Preservation Sys., Inc., 922 F.2d 801, 804 (Fed.Cir.1990). *See also Mathis*, 857 F.2d at 760 (interpreting 28 U.S.C. § 1961 to find that "[i]nterest on an attorney fee award . . . runs from the date of the judgment establishing the right to the award, not the date of the judgment establishing its quantum.").

Takeda is awarded interest accruing from the date of the Sanctions Opinion, September 20, 2006. Alphapharm's characterization of Takeda's request as a request for prejudgment interest is simply incorrect. Moreover, its reliance on *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576 (Fed.Cir.1991), is unpersuasive. *Beatrice* vacated an award of enhanced damages under 35 U.S.C. § 284 and noted that prejudgment interest under that section could be granted in any event only for the primary damage award and not for enhanced damages under Section 284. *Id.* at 1580. *Beatrice* did not address post-judgment interest for an award under Section 285. As such, it fails to support Alphapharm's argument that Takeda should not be awarded interest on the fee award granted today from the date of the Sanctions Opinion either under Section 285 or through this Court's inherent power.

Appendix C

CONCLUSION

Takeda is awarded attorney fees, expenses, and expert fees in the amount of $11,400,000 from Mylan and $5,400,000 from Alphapharm, with interest accruing from September 20, 2006 at a rate of 5.02%.

SO ORDERED.

Dated: New York, New York

March 21, 2007

DENISE COTE

United States District Judge

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING FILED JANUARY 23, 2009

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007-1269, -1270

(DCT - 03-CV-8253)

TAKEDA CHEMICAL

V

MYLAN LABS

ORDER

A petition for rehearing en banc having been filed by the Appellants,* and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

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* Petition filed by Alphapharm Pty., Ltd. and Genpharm, Inc.

Amicus Curiae, Generic Pharmaceutical Association was granted leave to file a brief in support of the Appellants' petition for rehearing en banc.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on January 30, 2009.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 01/23/2009

APPENDIX E — RELEVANT STATUTORY PROVSIONS

35 U.S.C. § 103. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 285. The court in exceptional cases may award reasonable attorney fees to the prevailing party.

Nos. 08-1461, 08-1463

Supreme Court, U.S.
FILED
JUL 29 2009
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

MYLAN LABS., INC., MYLAN PHARMACEUTICALS, INC., and UDL LABS., INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUS., LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

ALPHAPHARM PTY., LTD. and GENPHARM INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUS., LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, respondents state that Takeda Pharmaceuticals North America is wholly owned by Takeda Chemical Industries, Ltd. (now known as Takeda Pharmaceutical Company Limited), which, in turn, has neither a parent company nor a public-company owner of 10 percent or more of its stock.

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INTRODUCTION

The Federal Circuit affirmed a fact-specific, comprehensively explained determination by the district court that an award of compensatory attorneys' fees was warranted in this case for multiple reasons, including petitioners' bad faith filing of baseless Abbreviated New Drug Application ("ANDA") certifications which gave rise to these litigations, and petitioners' multiple acts of misconduct in the ensuing litigations. That litigation misconduct included violations of scheduling and discovery orders, the making and pressing of bad faith legal, factual and scientific contentions, and many other improper actions.

Both petitions for certiorari ignore these multiple, particularized findings which formed the basis for the fee awards. Instead, petitioners attempt to rewrite the lower court rulings to manufacture legal error that, in reality, does not exist. The core of both petitions is the assertion that fees were awarded merely because petitioners changed the theories set forth in their ANDA certifications (purportedly filed in good faith) by substituting new, supposedly well-grounded challenges advanced in good faith. The district court's detailed findings, however, show just the opposite: baselessness and bad faith, both with respect to petitioners' ANDA certifications and petitioners' actions and contentions during the course of the litigations. Those findings were upheld on appeal.

Both the district court and the court of appeals recognized that where a party has pursued litigation in good faith, a fee award is warranted only if that party has engaged in litigation misconduct. Pet. App. 16a-17a;

id. at 66a.[1] However, both courts found that good faith was lacking in this case. Thus, petitioners' assertions simply do not reflect the findings in this case.

The actual grounds of the decisions below are narrow and correct. They present no substantial legal question, much less a question warranting certiorari. For these and other reasons, including Alphapharm's failure properly to present its due process question below, review should be denied.[2]

STATEMENT OF THE CASE

I. Background

The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman"), "incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990). Hatch-Waxman mandates that ANDAs:

> shall contain . . . a *certification*, in the opinion of the applicant and to the best of his

1. "Pet. App. __" refers to the appendix to the petition in No. 1461. "JA__" and "A__" refer to portions of the Confidential Joint Appendix in the Federal Circuit Nos. 07-1269, -1270.

2. The two respondents are referred to collectively as "Takeda." The petitioners in No. 08-1461 are referred to as "Mylan," and the petitioners in No. 08-1463 as "Alphapharm." This Opposition will refer to Mylan's petition as "Pet.," and Alphapharm's as "APet." "Amicus" refers to the Brief of *Amicus Curiae* Generic Pharmaceutical Association in Support of Petitioners.

> knowledge, with respect to each patent which claims the listed drug . . . (I) that such patent information has not been filed; (II) that such patent has expired; (III) of the date on which such patent will expire; or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .

21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added). In addition:

> An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed.

Eli Lilly, 496 U.S. at 677-78 (citing 21 U.S.C. § 355(j)(2)(B)(iv)(II)). Pursuant to FDA regulations implementing this statute, the Section 355(j)(2)(B)(iv)(II) "Detailed Statement" "shall include . . . [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95.[3]

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3. Mylan's assertion that "the pre-suit Paragraph IV statement serves a limited notice function" (Pet. at 17) and that "absolutely nothing in Hatch-Waxman supports the court's conclusion that the pre-litigation administrative ANDA filing and notice letter must meet a *higher* threshold than a complaint in

(Cont'd)

Mylan and Alphapharm filed 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") certifications, certifying to FDA that, in their opinions and to the best of their knowledge, U.S. Patent No. 4,687,777 (the "'777 patent"), covering the active ingredient in Takeda's ACTOS® product (pioglitazone), was invalid. Mylan and Alphapharm sent Takeda 21 U.S.C. § 355(j)(2)(B) "Paragraph IV Notice" letters purporting to include Detailed Statements, stating the factual and legal bases supporting their invalidity allegations. Pet. App. 155a-60a; A4983-5009; A6648-62.

Takeda brought suit under 21 U.S.C. § 355(j)(5)(B)(iii) against Mylan and Alphapharm. After considering all

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(Cont'd)

civil litigation," turns the plain language of the statute on its head. Pet. at 16 (emphasis in original); *see* Pet. at 18; *see also* APet. at 2, 11. Hatch-Waxman's requirement for a "detailed statement" clearly does impose a higher threshold than the "short and plain statement of the claim" required under Fed. R. Civ. P. 8, even considering the Court's recent explanation of what is needed to survive a motion to dismiss (*Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009)). *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II) (Pet. App. 250a); 21 C.F.R. § 314.95(c)(6) (Pet. App. 280a). Mylan posits that "[a]s long as an ANDA applicant has complied with the filing requirements of the statute and presented colorable arguments, it has discharged Congress's purpose." Pet. 18. Even if all Congress intended by requiring a "detailed statement of the factual and legal basis" for the applicant's opinions was that the applicant simply had to come up with "colorable arguments," Mylan did not do so here — its Statement was held to be "baseless and filed in bad faith." Pet. App. 101a; *see id.* at 15a.

the evidence at trial, the court issued a 124-page opinion rejecting petitioners' challenges to the '777 patent, holding that "both Alphapharm and Mylan have failed to make even a rudimentary showing that the invention was obvious or that Takeda engaged in inequitable conduct." Pet. App. 113a; *see generally*, *id.* at 111a-227a (reported at 417 F. Supp. 2d 341 (S.D.N.Y. 2006)). The court entered judgment for Takeda on March 13, 2006. A125-28. Mylan and Alphapharm appealed that judgment, including, inter alia, the district court's February 21, 2006 Opinion and Order on the merits (Pet. App. 111a-227a), and "all opinions, orders, and rulings subsumed therein or made prior thereto." A6286-88; JA9451-54. The court of appeals affirmed, rejecting Alphapharm's challenge in a published opinion (492 F.3d 1350 (Fed. Cir. 2007)), and Mylan's challenge by summary order (Pet. App. 26a; *see id.* at 5a). Mylan did not seek a writ of certiorari therefrom, but Alphapharm did. This Court denied Alphapharm's petition for a writ of certiorari on March 31, 2008. 128 S. Ct. 1739. Thus all parts of the judgment on the petitioners' respective merits cases are now final.

A. The District Court Decisions

Following entry of judgment on the underlying merits, Takeda requested an award of attorneys' fees under 35 U.S.C. § 285. The court granted Takeda's request, finding that Takeda had shown petitioners' respective bad faith and litigation misconduct by clear and convincing evidence, and that petitioners' "misconduct was exceptional and fully justifies the award of attorneys' fees." Pet. App. 64a; *see generally*, *id.*, 61a-110a.

The district court subsequently determined the amount of fees in a separate opinion. *Id.* at 27a-60a. The court relied on the well-accepted "lodestar" analysis, representing hours spent times a reasonable hourly fee, plus expenses. The award was made without enhancement, even though the district court noted that an enhancement would be justified by petitioners' "outrageous litigation conduct," noting that petitioners "increased the cost and burden of this litigation through their shifting theories of attack, none of which was meritorious or adopted in good faith," and none of which "reflected a careful analysis of the relevant documents and the application of sound science to that analysis." *Id.* at 52a; *see also id.* at 58a (petitioners "well understood that their attacks on the '777 Patent were groundless and would only succeed if Takeda did not expend the effort and resources necessary to shine a light on the flaws in the [petitioners'] arguments and if the Court did not spend the time necessary to learn the relevant science and understand the evidentiary record created by the trial submissions"). Thus, the district court calculated the "compensatory quantum of the award" based on the "level of exceptionality rising out of the offender's particular conduct," *id.* at 35a (quoting *Mathis v. Spears*, 857 F.2d 749, 754 (Fed. Cir. 1988)), under a careful application of this Court's precedents. *See, e.g.*, Pet. App. 31a-37a (applying *City of Burlington v. Dague*, 505 U.S. 557, 559 (1992); *Blanchard v. Bergeron*, 489 U.S. 87, 94 (1989); *Farrar v. Hobby*, 506 U.S. 103, 114 (1992); *Hensley v. Eckerhart*, 461 U.S. 424, 429-30 n.3 (1983)). The court also explained that "the litigation was equivalent to two atypical and massive patent cases." Pet. App. 41a (footnote omitted). The respective awards against Mylan and Alphapharm were well within the range of the "5 to 12 million dollars" that, according to Mylan's Rule 30(b)(6) testimony, is what generic pharmaceutical companies

anticipate spending on their own legal fees in an ANDA case. Pet. App. 41a n.13; JA3229 (126:4-13).[4] The court additionally awarded Takeda its reasonable expert fees under its inherent powers as a sanction for petitioners' bad faith conduct in the litigation. Pet. App. 56a-58a.

B. The Federal Circuit's Affirmance

Mylan and Alphapharm separately appealed that fee award to the Federal Circuit. The Federal Circuit affirmed, concluding that "the district court did not clearly err in finding that this was an exceptional case because of the misconduct by Mylan and Alphapharm and did not abuse its discretion in awarding attorney fees . . . ." *Id.* at 3a; *see generally, id.* at 1a-25a. The court also rejected challenges to the amount of attorneys' fees and to the award of expert fees – issues not raised in this Court. *Id.* at 17a-20a. Judge Bryson concurred, discussing only the expert-fees issue.[5] *Id.* at 21a-25a. The Federal Circuit denied petitioners' requests for rehearing en banc, without dissent. *Id.* at 245a-46a.

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4. As Mylan has previously acknowledged, a generic company challenging a patent in an ANDA litigation would ordinarily incur "far less" in attorneys' fees than the patentee. Pet. App. 45a.

5. Judge Bryson's concurring opinion did not "acknowledge[] . . . a punitive aspect" in the district court's Section 285 award, as Mylan suggests. *Cf.* Pet. at 19. Judge Bryson, after discussing the uncertain bounds of a court's inherent authority to award expert fees as a sanction, concluded that the court's award of expert fees did not result in a greater total fee award because the district court alternatively stated that it would and could have granted an enhancement of the attorneys' fee award to Takeda. Pet. App. 25a. Neither petition's question presented raises a challenge to the expert-fee award.

II. Mylan's Baseless Certification, Bad Faith, and Litigation Misconduct

Mylan filed its ANDA containing a Paragraph IV certification on the first day it could file, July 15, 2003, in order to garner first-to-file status and thus obtain 180-day exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv).[6] On September 8, 2003, Mylan sent Takeda its Paragraph IV Notice letter and Detailed Statement, which asserted that pioglitazone (a 2-pyridyl thiazolidinedione) would have been obvious over so-called compound 14 (a 2-phenyl thiazolidinedione) of a Takeda publication which had been considered by the Patent Examiner who allowed the '777 patent. Mylan's theory of obviousness was based on a scientifically unsupportable contention that pyridine and benzene are supposedly "bioisosteres."[7] A4989-92; *see* Pet. App.

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6. Mylan attempted to ensure its first-to-file status by stationing a line-stander outside the FDA, 24-hours-a-day, 7-days-a-week, more than six-weeks before the first date to file an ANDA for pioglitazone. While Mylan claims to have obtained a legal opinion in support of its eventual Paragraph IV certification (no such opinion was ever produced), it admittedly did not do so until four days before it filed its ANDA. Pet. App. 95a-96a; JA233 (110:19-111:21); JA235; *see also* JA226-27 (37:19-38:3); JA228 (47:13-19); JA216 (21:4-8). Incidentally, FDA demanded that Mylan's line-stander leave the premises. Pet. App. 95a n.26.

7. The pertinent chemistry, and the law of chemical obviousness in view of this Court's decision in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), is discussed in detail in the district court's opinion and Federal Circuit's affirmance on the underlying merits, which is now final, and will not be repeated in detail herein. *See* Pet. App. 111a-227a, *aff'd*, No. 06-1364 (*per curiam*), No. 06-1329, 492 F.3d 1350 (Fed. Cir. 2007), *reh'g and reh'g en banc denied* (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1739 (2008).

155a-60a; A4983-5009; A6648-62. Mylan stonewalled Takeda concerning the factual basis for the position set forth in its Statement. Pet. App. 96a; *id.* at 228a-41a, 242a-44a. Only after fact discovery closed, and having been twice ordered by the court, did Mylan produce a Rule 30(b)(6) designee to testify regarding the contentions in its Statement. *Id.* at 231a-32a. At that deposition, Mylan's Rule 30(b)(6) designee admitted that no reason existed to select compound 14 as a lead compound. *Id.* at 15a, 99a; JA221 (239:19-240:16). Asserting privilege, Mylan's counsel refused to allow examination on any theory not in the Detailed Statement. Pet. App. 231a-32a. Then, three days after that deposition and a week after the close of fact discovery, Mylan untimely served "supplemental" responses to Takeda's interrogatories in which Mylan abandoned the compound 14 "bioisostere" theory of its Detailed Statement and instead asserted a brand new theory that pioglitazone would have been obvious "on the basis of compound 57," even though Mylan's 30(b)(6) witness had just days earlier testified that an analysis of the toxicity and efficacy profile of compound 57 would have "ruled it out" as a lead compound. *Id.* at 96a-97a, 232a, 228a-241a; JA218 (134:7-15) (testifying that Sohda reference "would and should cause one to rule [compound 57] out."). By changing theories after the close of discovery, and cutting off questions on any new theory, Mylan attempted to preclude Takeda from discovery regarding its entirely new theory of the case.

The district court precluded Mylan from advancing this new theory at trial because Mylan's untimely supplementation of its theory violated the court's "specific judicial directive for the timing of discovery."

Pet. App. 243-44a (quoting *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 551 (Fed. Cir. 1998)); *see generally* Pet. App. 242a-44a, 228a-41a.[8] At the same time, the district court did permit Mylan to amend its answer and counterclaims to plead a third new theory, inequitable conduct, "despite Mylan's tactical maneuvers, designed to hamstring Takeda . . . ." *Id.* at 103a.

On Takeda's motion for fees, the district court found not only that "Mylan's certification letter was filed in bad faith and with no reasonable basis to claim the '777 patent invalid" (*id.* at 95a), but that Mylan also committed "numerous" acts of "litigation misconduct" in pursuing an "always frivolous" inequitable conduct

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8. Mylan contends that the district court "forbade Mylan's use of an obviousness theory other than the one stated in its [ANDA] notice letter." Pet. 6-7 (citing Pet. App. 242a-244a, 228a-241a). To the extent Mylan suggests that the district court deemed it improper for Mylan to make any change from the notice-letter theory, that suggestion is false. The district court specifically noted:

> Although as a general matter an ANDA applicant may be able to assert theories other than those outlined in a notification letter, 'when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs the trial . . . . [A] specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound.'

Pet. App. 243a-44a (quoting *Lydall, Inc.*, 159 F.3d at 551); *see id.* at 228a-241a (opinion denying reconsideration, explaining why Mylan had no excuse for its late raising of new theory); *see id.* at 97a (describing rulings). That ruling, as part of the merits judgment, is now final.

claim, and that "the totality of the circumstances, including other instances of Mylan's untimely conduct, justified the award of attorney fees against Mylan . . . ." *Id.* at 6a; *id.* at 64a (noting Mylan "engaged in other litigation misconduct" that "was exceptional and fully justifies the award of attorneys' fees."); *see also id.* at 95a-107a.

The district court found that Mylan's inequitable conduct claim was advanced "without a reasonable basis and in bad faith." *Id.* at 106a. "Mylan never had any evidence of wrongful intent by Takeda, and despite promises at trial that it would produce some, utterly failed to do so." *Id.* at 102a. Noting that Mylan made factual assertions that were "absolutely false and misleading," "particularly egregious," and "inexcusable" (*id.* at 104a-06a), the court found that Mylan engaged in seven distinct categories of litigation misconduct in pursuing its inequitable conduct claim.[9] *Id.* at 101a-07a.

The court of appeals affirmed, observing that "Mylan's invalidity argument in its certification letter appears even more baseless than Alphapharm's." *Id.* at 15a. Noting "the scientific errors present in Mylan's certification letter," the court concluded that the district court "had ample reason to hold that Mylan's certification letter was filed in bad faith and with no

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9. Mylan "present[ed] no defense" to three of the seven before the district court, nor did it challenge any of those findings before the Federal Circuit. Pet. App. 101a-02a, 106a-07a. Mylan does not even address these multiple and well-supported findings of litigation misconduct in its petition.

reasonable basis to claim the '777 patent invalid." *Id.* "Similarly, the finding that Mylan engaged in litigation misconduct was well-supported and explained by the district court." *Id.*

The Federal Circuit directly rejected Mylan's characterization of the district court's ruling as having based its fee awards on "the mere fact that Mylan changed its theory of invalidity and then lost." *Id.* at 16a. The court explained:

> Rather, the court determined that Mylan's initial certification letter was completely baseless and that the claims Mylan offered as substitutes were similarly frivolous.

Id. For much the same reason, the court rejected the argument that the fee award will chill ANDA filings, recognizing that the district court's award was based on case-specific "baseless certification letters compounded with litigation misconduct." *Id.*; *see id.* at 16a-17a. The Federal Circuit did not "predicate[] its award on a legal standard that no other court of appeals applies to fee awards and that frustrates the very purpose of the Hatch-Waxman Act." Pet. at 10. Rather, the court predicated its affirmance on the district court's detailed findings of Mylan's baseless, bad faith certification and litigation misconduct.

III. Alphapharm's Baseless Certification, Bad Faith, and Litigation Misconduct

Alphapharm also filed its ANDA containing a Paragraph IV Certification on July 15, 2003.[10] Alphapharm's January 29, 2004 Paragraph IV Notice letter and Detailed Statement alleged that pioglitazone would have been obvious over prior art compound (b) as described in the '777 patent itself, but failed to identify any reason that the skilled artisan would select compound (b) as a "lead" or "development" compound from the many other compounds disclosed in the prior art. Pet. App. 9a-10a; 74a-77a; *see id.* at 185a, *aff'd*, 492 F.3d 1350. In a "stunning admission" of impermissible hindsight (*id.* at 76a), Alphapharm's first Rule 30(b)(6) witness on this topic, Dr. Rosenberg, conceded that "he only chose compound (b)" as a basis for attacking the patentability of pioglitazone "because it was similar to pioglitazone." *Id.* at 179a; *see id.* at 76a; A2224 (169:17-18). *But see KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) ("warning against a 'temptation to read into the prior art the teachings of the invention in issue' and instructing courts to 'guard against slipping into the use of hindsight'")). He further "admitted that there was 'nothing to recommend' compound (b) over any of the other compounds" in the article that had the same efficacy rating. Pet. App. 179a, *aff'd*, 492 F.3d at 1358-59; Pet. App. 76a-77a, 80a, 88a; A2225 (172:10-20). In addition, Rosenberg admitted in his deposition that

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10. Although Alphapharm's ANDA was the first-filed, FDA rejected it because Alphapharm failed to make a pharmaceutical that was bioequivalent to ACTOS® — the commercial name of Takeda's drug. Pet. App. 154a n.27.

pioglitazone is "clearly superior" to the closest prior art, and that "Table 1 of the '777 [p]atent established that clear superiority." Pet. App. 88a; *see id.* at 197a, *aff'd*, 492 F.3d at 1361-62; A2241 (235:8-236:4).

Alphapharm's next Rule 30(b)(6) designee, Barry Spencer, came up with an entirely different analysis, testifying that the person of ordinary skill would actually have chosen to investigate three different prior art compounds, including compound (b). Pet. App. 84a; A6082 (58:12-59:13). Next, Alphapharm's trial expert, Mosberg, contended in his expert report that the person skilled in the art would have chosen compound (b) as the lead compound based on prior art patents. However, at his deposition, Mosberg acknowledged that a person of ordinary skill in the art would *not* have focused particularly on compound (b), claiming instead that the person of ordinary skill in the art would have engaged in a research program designed to investigate various permutations on *all* of the prior art 2-pyridyl, 3-pyridyl, and 4-pyridyl compounds (although with a higher priority on 2-pyridyl and 3-pyridyl). Pet. App. 85a-86a; *id.* at 184-85a; A3144 (1189:4-14); A3146 (1192:10-14). At trial, Mosberg "turned the identification of a lead compound on its head." Pet. App. 86a. "[C]onfronted with the many problems associated with the identification of compound (b) as a lead compound," Mosberg nevertheless contended it would be the lead compound, not based on analytical or scientific reasoning, but "because Takeda was *not* actively pursuing it . . . ." *Id.* (emphasis in original); *see id.* at 179a-80a, 180a n.54; A3143 (1187:16)-3144 (1188:25); A3148 (1195:6)-3149 (1197:2).

On Takeda's motion for fees, the district court found that Alphapharm's ANDA certification was "so devoid of merit and so completely fails to establish a prima facie case of invalidity that it must be described as 'baseless.'" Pet. App. 73a; *see id.* at 5a. The court noted that Alphapharm's eventual obviousness contention at trial was that a skilled artisan would have started with one particular prior-art compound and then varied it in two (supposedly obvious) ways. *Id.* at 74a. Alphapharm was never able to come up with any reasonable basis for its crucial premise – that a skilled artisan would have started with that compound in the face of stark reasons (such as its toxicity) *not* to start with that compound. *Id.* at 74a-79a. Alphapharm's ANDA certification also made "baseless," "unsupportable" characterizations of the data presented in the '777 patent (*id.* at 79a-82a), and failed to address "secondary considerations" that are part of a proper obviousness analysis. *Id.* at 82a. Taken together, the court found the deficiencies in Alphapharm's certification to be "so glaring" as to disprove due care in making any case of obviousness. *Id.*

The court then recounted Alphapharm's groundless efforts to find a new obviousness theory during the litigation.[11] That misconduct included naked reliance on pure hindsight, *i.e.*, working backwards from

11. Alphapharm asserts that "[t]here was never any shift in Alphapharm's position." APet. 7-8. Even at the time of the merits determination, the district court found that "[Alphapharm] has presented a constantly shifting set of arguments, abandoning some, inventing others, and even contradicting itself as the trial progressed." Pet. App. 169a n.37; *see also id.* at 172a n.42; *id.* at 175a n.47.

pioglitazone, because *without* such hindsight, the skilled artisan had no basis either to select the specific alleged starting compound or to undertake the two specific modifications to arrive at pioglitazone, which was Takeda's discovery. *Id.* at 83a-90a, 86a ("without any analytical or scientific support"), 87a ("utterly indefensible"). The court held that Alphapharm's legal analysis was "flat wrong," and found that its response to the "damning recitation" of its "ever-shifting collage of arguments in a futile search for a coherent theory of obviousness . . . underscores its bad faith." *Id.* 83a-86a. The court also found that it was improper of Alphapharm to continue to dispute the superiority of pioglitazone to the closest prior art after Rosenberg admitted that pioglitazone was "clearly superior" to compound (b). *Id.* at 88a. Alphapharm simply did not have "a credible claim of obviousness." *Id.* at 92a. Finally, the court found that, although Alphapharm had pled only invalidity based on obviousness, it tried to insert a challenge of unenforceability based on alleged deception of the PTO (inequitable conduct), causing confusion and further waste of time. Alphapharm's arguments on this issue "were entirely frivolous." *Id.* at 90a, 91a. In sum, the court held that:

> Alphapharm's Section 355 Statement was deeply flawed, filed in bad faith, and failed to present even a prima facie case of invalidity. Alphapharm made these proceedings far more complex and expensive by constantly shifting its theory of obviousness in a futile effort to locate a coherent argument. Even in response to this motion [for attorneys' fees], it has misrepresented the record in this litigation.

> This is the exceptional case where an examination of the totality of the circumstances amply justifies, indeed compels, the award of attorneys' fees.

Id. at 94a. The district court additionally found that Alphapharm's "unilateral decision" to disregard discovery orders in connection with its untimely and improper assertion of an advice of counsel defense in response to Takeda's motion for attorney's fees was "vexatious and constitutes litigation misconduct." *Id.* at 71-73a.

The court of appeals affirmed. *Id.* at 1a-25a. The Federal Circuit recognized, like the district court, that Alphapharm's ANDA certification "failed to provide any reason" that a skilled artisan would have identified the particular alleged starting-point compound "and thus did not make a prima facie case of obviousness based on the structural similarity between compound (b) and pioglitazone." *Id.* at 10a.; *see id.* at 9a-11a.[12] The court specifically noted that the district court had not "faulted Alphapharm simply for changing its obviousness argument at trial from the theory advanced in the Paragraph IV letter. Rather, the [district] court

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12. The court noted that, in the merits affirmance on non-obviousness, Judge Dyk wrote a separate concurring opinion, but only to question the possible overbreadth of two patent claims; the concurrence did not question the failure of Alphapharm's prima facie case based on compound (b), the particular alleged starting-point compound in Alphapharm's Statement, as Alphapharm contends. Pet. App. 10a. The fact of Judge Dyk's separate opinion thus does not suggest the reasonableness of Alphapharm's certification.

methodically examined a number of shortcomings in Alphapharm's Paragraph IV letter, which were made obvious by Alphapharm's 'constantly shifting set of arguments' that supported the finding that the certification was baseless." *Id.* at 10a; *see id.* at 11a. The court of appeals explained that these findings amply established the lack of basis for Alphapharm's Paragraph IV certification, which together with litigation misconduct, fully warranted the Section 285 award. *Id.* at 11a-13a.

ARGUMENT

The decision of the court of appeals is mischaracterized by petitioners. It is based on the particularized facts of these cases, and does not rest on the grounds petitioners assert. It creates no inter- or intra-circuit conflict, and threatens none of the consequences petitioners claim. Rather, in a highly fact-specific determination, it relies upon multiple and independent findings of petitioners' bad faith, baseless claims and litigation misconduct. Those findings are not challenged, are correct and well-supported in the record, and would not warrant review in any event. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949), *aff'd on reh'g*, 339 U.S. 605 (1950) ("A court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error."). Moreover, Alphapharm did not preserve (in either court below) its new due process question. For these and other reasons, the petitions should be denied.

I. Mylan's Petition Should Be Denied

A. The Federal Circuit Correctly Affirmed the District Court's Findings of Litigation Misconduct

In its petition, Mylan does not challenge the Federal Circuit's affirmance of the district court's findings that Mylan "decided to challenge the validity of the '777 Patent without any good faith basis to do so" (Pet. App. 95a) and "engaged in a host of bad faith litigation tactics" over the course of the litigation which ensued (*id.* at 57a). Mylan further does not challenge the Federal Circuit's conclusion that "the totality of the circumstances, including other instances of Mylan's untimely conduct, justified the award of attorney fees . . . ." Pet. App. 6a. Instead, Mylan entirely ignores its own litigation misconduct and the district court's analysis of the totality of the circumstances, and accuses the Federal Circuit of error in upholding the district court's award "on the ground that Mylan litigated a theory of patent invalidity that it had developed after discovery, rather than the pre-litigation legal theory it had advanced [in its Paragraph IV Notice letter and Statement]." Pet. at 10.

The Federal Circuit did not affirm based on the "mere fact that Mylan changed its theory of invalidity." Rather, the Federal Circuit affirmed the district court's "determin[ation] that Mylan's initial certification was completely baseless and that the claims Mylan offered as substitutes were similarly frivolous." Pet. App. 16a. The Federal Circuit expressly noted:

> We do not find persuasive Mylan's argument that the district court took issue with the mere

> fact that Mylan changed its theory of invalidity and then lost. Rather, the court determined that Mylan's initial certification letter was completely baseless and that the claims Mylan offered as substitutes were similarly frivolous. In short, the district court, which was in the best position to evaluate the entire strategy pursued by Mylan, did not commit clear error in finding litigation misconduct.

Pet. App. 16a.

Thus the district court did not, as Mylan misleadingly suggests, "substantially" base its award on the mere fact that "Mylan had not pursued the case on the theory of invalidity set forth in its initial pre-suit notice letter, which the district court deemed meritless." Pet. at 3. In fact, the district court enumerated seven distinct categories of Mylan's misconduct during the litigation, misconduct which Mylan now ignores.

The Federal Circuit also did not announce a standard that would restrict ANDA filers to "only allege at trial the exact defenses as presented in its pre-litigation ANDA certification rather than pursue defenses that confirm to the evidence developed through discovery and presented at trial." Amicus at 3; *see* Pet. at 10-11. On the contrary, the district court granted Mylan leave to amend its answer and counterclaims to plead inequitable conduct, a defense wholly absent from its Detailed Statement. The court allowed Mylan's motion to add this defense after the close of fact discovery, "[d]espite Mylan's tactical maneuvers, designed to

hamstring Takeda's ability to confront this new theory . . . ." Pet. App. 103a. Moreover, in precluding Mylan from untimely asserting its "revised" obviousness theory, the district court explicitly recognized that "as a general matter an ANDA applicant may be able to assert theories other than those outlined in a notification letter." *Id.* at 243a-44a. The district court precluded Mylan from asserting a new theory of obviousness – not because that theory was absent from Mylan's Statement – but because it was untimely asserted after the close of fact discovery, and in violation of the court's discovery orders. *Id.* (quoting *Lydall, Inc.*, 159 F.3d at 551) (noting "when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs the trial . . . . [A] specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound."); *see* Pet. App. at 228a-241a (discussing Mylan's "specious" arguments on a motion for reconsideration). Mylan cannot seek to avail itself of the breadth of discovery permitted under the Federal Rules, while ignoring, and in many cases violating, other limitations imposed by the Rules.[13] *Cf.* Pet. at 10-11; *see* Pet. App. 243a-44a.

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13. In light of the Federal Circuit's affirmance of the district court's fact-intensive analysis of the totality of the circumstances, Mylan's reliance on *Merck & Co. v. Mylan Pharms., Inc.*, 79 F. Supp. 2d 552, 556 (E.D. Pa. 2000) is inapposite. *Cf.* Pet at 13. In *Merck*, "good faith persistence" was not a basis for sanctions. *Merck*, 79 F. Supp. 2d at 556. Here, Mylan's "particularly egregious . . . and inexcusable" conduct was a valid basis for sanctions. Pet. App. 104a.

B. The Federal Circuit Correctly Affirmed the District Court's Findings of Mylan's Bad Faith

The Federal Circuit did not adopt or apply an incorrect standard in reviewing the district court's findings that Mylan made its Paragraph IV certification — and proceeded to litigate the ensuing case — in bad faith. *Cf.* Pet. at 16-18. Although Mylan may have abandoned the theory advanced in its Statement before trial, Mylan is incorrect to state that this theory was "unlitigated," *id.* at 14, or was "largely irrelevant" once in litigation, *id.* at 17. Mylan abandoned this theory *after* the close of discovery, and *after* its 30(b)(6) designee's admission confirmed just how baseless it was. Pet. App. 95a-101a; *id.* at 159a-60a; *see id.* at 242a-44a; *id.* at 228a-41a. Takeda established Mylan's bad faith in connection with its Paragraph IV certification and Statement by clear and convincing evidence, including admissions from Mylan's witnesses, JA233 (110:19-111:21); JA226-27 (37:19-38:3); JA228 (47:13-19); JA216 (21:4-8), and testimony of Takeda's and Alphapharm's experts, JA221 (239:19-240:16); JA296-323; JA483-84 (324:8-325:9); JA8302-05; JA8332-36. *See generally*, Pet. App. 1a-110a. Mylan's arguments advanced in defense of its Paragraph IV certification were, at best, "utterly frivolous," and themselves were "further evidence that an award of attorney' fees against Mylan is appropriate." *Id.* at 99a.

Moreover, the district court found that Mylan's bad faith was pervasive throughout the litigation:

> Mylan engaged in a host of bad faith litigation tactics, which increased the burden of this

> litigation enormously. These included the presentation of factually indefensible positions from its ANDA filing straight through to its submissions in opposition to the motion for sanctions.

Pet. App. 57a; *see Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000) (concluding "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed warranted the district court's finding that this case was exceptional."); *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349-51 (Fed. Cir. 2004).

Contrary to Mylan's suggestion, the lower courts did not "[c]onstrue Section 285 to allow an inference of bad faith because an ANDA applicant properly changed positions based on discovery . . . ."[14] Pet. at 14. The district court found, and the Federal Circuit affirmed, that Mylan's conduct was anything but "proper." The court of appeals affirmed that Mylan precipitated this litigation with a "baseless" certification (Pet. App. 101a), advanced "absolutely frivolous" (*id.* at 97a) and "extremely misleading" arguments in support of its "aborted effort to make a wholesale revision to its

14. Mylan's generalized argument that *some* patent defenses require discovery before they can be asserted has no application to this case. *Cf.* Pet. at 12-13. The baseless obviousness argument Mylan chose to advance in its Statement relied on two publicly-available prior art references. A4983-5009. Thus, Mylan's suggestion that the possibility that discovery may shed some light on certain defenses somehow excuses a baseless Detailed Statement is a non-sequitur.

obviousness theory" (*id.* at 100a), and "propounded a frivolous claim of inequitable conduct" (*id.* at 95a). These positions did not "become untenable" in light of discovery, nor were its "new claims" "revealed" or "bolstered" through discovery. *Cf.* Pet. at 11-12. These positions were advanced without a reasonable basis and in bad faith, and no reading of the Federal Rules can condone such litigation misconduct. "The framework established by Congress for accelerating the approval process for generic versions of established drugs . . . is not an invitation to frivolous, bad faith attacks on patents." Pet. App. 64a.

C. Hatch-Waxman Cannot Be Read to Condone Mylan's Bad Faith

Mylan's argument that exposing ANDA filers to an award of attorneys' fees under Section 285 somehow "conflicts with the special litigation process" of Hatch-Waxman is contrary to the plain language of the statute. *Cf.* Pet. at 19. While proscribing money damages for *infringement*, Section 202 of Hatch-Waxman, codified at 35 U.S.C. § 271(e)(4), explicitly provides that "[f]or an act of infringement described in [35 U.S.C. § 271(e)(2)] . . . a court may award attorney fees under [35 U.S.C.] section 285." Hatch-Waxman thus expressly approves fee awards under the standards of Section 285, which are amply satisfied here.

Moreover, Mylan's argument that allowing the Federal Circuit's decision to stand will undercut the policies of Hatch-Waxman is unfounded. Mylan's generalized policy arguments ignore the totality of the circumstances in this case. The award in this case was

specifically tailored to the petitioners' misconduct in this case, and will not "chill the ANDA process." As the Federal Circuit held:

> [W]e find the "chilling" argument regarding ANDA filers advanced by Alphapharm and Mylan to be unpersuasive, despite the support provided by the amicus filing of the Generic Pharmaceutical Association. In making a Paragraph IV certification, appellants are statutorily required to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid." 21 U.S.C. § 355(j)(2)(B)(iv)(II) (2006). It is clear from the district court's opinion that it was not faulting Alphapharm or Mylan for the act of filing an ANDA that challenged the pioglitazone patent, nor did it limit the filers to the theories raised in their certification letters. Rather, the district court found the case exceptional based on the specific circumstances involved in this case, viz., baseless certification letters compounded with litigation misconduct. In fact, the district court addressed the deterrence argument directly:
>
> > There is no basis to find that this award will deter ANDA filings and litigation. This award addresses baseless ANDA filings and the pursuit of frivolous ANDA litigation in bad faith and other litigation

> misconduct. The Hatch-Waxman Act cannot be read to immunize such conduct.
>
> Given the court's specific articulation that its ruling was directed toward baseless ANDA filings and litigation in bad faith, we decline to disturb the court's finding of an exceptional case as potentially chilling non-frivolous ANDA filings under the Hatch-Waxman Act. Well-supported filings challenging the validity and infringement of patents owned by an NDA holder should not raise the specter of an unjustified holding of an exceptional case.

Pet. App. 16a-17a (quoting *id.* at 108a). To hold otherwise would disturb the balance between innovator and generic interests that Congress intended in enacting Hatch-Waxman:

> There is a strong public interest, as acknowledged by the statutory scheme, in challenging patents that keep the price of pharmaceuticals high. There should be no incentive, however, for litigation that is prolonged and complicated by a series of attacks undertaken without a good faith basis and without a sound basis in science. Science, medical research, and the court system demand better.

Pet. App. 53a; *see* H.R. Rep. No. 98-857, pt. 1 at 14-15 (1984, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48).

II. Alphapharm's Petition Should Be Denied

Alphapharm seeks certiorari on the question whether the fee award constitutes punishment in violation of its due process rights. The petition should be denied for multiple reasons.

A. Alphapharm's Current Due Process Claim Was Neither Addressed Nor Preserved Below

Neither the court of appeals nor the district court decided a due process issue. There is accordingly no due process ruling, express or implicit, for this Court to review.

The reason for the absence of a due process ruling below is apparent. Alphapharm did not adequately present or preserve any due process question, either before the district court or the court of appeals. *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 78-79 (1988); *G.D. Searle & Co. v. Cohn*, 455 U.S. 404, 412 (1982); *see also United States v. Ortiz*, 422 U.S. 891, 898 (1975). Alphapharm's opening brief before the court of appeals, where all issues must be raised, presented no due process issue. *Pieczenik v. Dyax Corp.*, 265 F.3d 1329, 1332-33 (Fed. Cir. 2001) ("It is well settled that an appellant is not permitted to make new arguments that it did not make in its opening brief.").[15] Alphapharm has thus waived its due process claim.

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15. Alphapharm raised a due process issue in its rehearing petition, but that is too late where, as here, it is not the court of appeals' ruling, but the district court's ruling, that is asserted to be unconstitutional. *See Bankers Life & Cas. Co.*, 486 U.S. at 78-79. Alphapharm's reply brief to the panel inserted the words

(Cont'd)

B. There Has Been No Deprivation of Due Process

Even had it been properly preserved, the premise of Alphapharm's due process argument is inapplicable to this case. The fee award is not "punishment" or "punitive." As Mylan's own petition expressly recognizes (08-1461 Pet. 19), attorneys' fees under Section 285 are compensatory, not punitive. *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1347 (Fed. Cir. 2004) (en banc) (noting "Attorney fees are compensatory . . . ."); *see also Hensley*, 461 U.S. at 435 (noting "[w]here a plaintiff has obtained excellent results, his attorney should recover a fully compensatory fee."). That is plainly the case of the fee award in this case. The district court expressly noted that the amount awarded to Takeda was required to compensate Takeda for having to defend against petitioners' "shifting theories of attack, none of which was meritorious or adopted in good faith" or "reflected a careful analysis of the relevant documents and the application of sound science to that analysis." Pet. App. 52a; *id.* at 27a-60a. There is nothing "punitive" about making Alphapharm

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(Cont'd)

"due process" into a quote that it used to argue unfairness. That action did not raise a due process issue – which, in any event, would have been too late given the settled rule that an appellant cannot raise new legal arguments in reply. *Optivus Tech., Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 989 (Fed. Cir. 2006); *Pieczenik*, 265 F.3d at 1333.

pay for the actual consequences of its unjustifiable litigation misconduct.[16]

Furthermore, such an award is not a due process violation – or unauthorized by Section 285.[17] Alphapharm cites only due-process decisions involving "punishment," rather than compensation. Neither the Constitution nor Section 285 bars the shifting of actual litigation expenses to a party that causes them through the actions

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16. The court also did not "penalize" Alphapharm for "following the rules applicable to all patent cases." APet. at 9. "The purpose of § 282, like that of the Federal Rules, is to prevent unfair and prejudicial surprise, not to facilitate last-minute production of evidence." *Lydall, Inc.*, 159 F.3d at 551. "Thus although § 282 sets a minimum period for the identification of prior art to be introduced . . . , a specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound." *Id.; see supra* note 8.

17. From the outset of the case, Alphapharm was on notice that Takeda sought an award of attorneys' fees under Section 285. Pet. App. 69a. The "duty of care" required of an ANDA certifier was imposed by Hatch-Waxman in 1984. *See Yamanouchi*, 231 F.3d at 1346 (noting "the [Hatch-Waxman] Act unambiguously permits an award of attorneys fees to the prevailing party in exceptional cases on the basis of an ANDA filing."). The Federal Circuit clearly articulated that "[m]isconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that follow[s] warrant[s] [a] district court's finding that [a] case was exceptional." *Yamanouchi*, 231 F.3d at 1347; *Glaxo*, 376 F.3d at 1350 (noting "[s]uch unjustified litigation misconduct has always justified a finding of an exceptional case."). Even according to the Amicus, "[t]o be sure, an ANDA applicant owes a duty of care in making its certification and providing the basis of that certification to the patent owner . . . ." Amicus at 7.

that the district court properly found here: initiation of the Hatch-Waxman process by filing a "baseless" notice of alleged invalidity for obviousness, in breach of an undisputed duty of care and in bad faith (Pet. App. 73a, 74a, 94a), followed by bad faith and vexatious litigation, including presentation of shifting new obviousness theories that themselves were "utterly indefensible" for lack of a responsible scientific basis (*id.* at 87a; *see id.* at 83a-90a), and presentation of "entirely frivolous" charges that Takeda deceived the PTO (*id.* at 90a-91a). *See generally, id.* at 67a-94a. As already explained *supra*, the courts below did not award fees for filing a good-faith ANDA certification and thereafter substituting reasonably grounded theories in good-faith litigation. *See, e.g., id.* at 10a. (noting "we do not believe that the district court faulted Alphapharm for simply changing its obviousness argument at trial from the theory advanced in the Paragraph IV letter."). Alphapharm's attempt to portray the rulings below as so holding is as off-base as Mylan's similar attempt. *See id.* at 10a-11a

C. Alphapharm Cannot Ignore the Commercial Success that Motivated Its ANDA Filing

As one part of its due process grievance, Alphapharm argues that the district court erred in "sanction[ing] Alphapharm in part because Alphapharm's Notice Letter failed to address commercial success . . . ." APet. 12. As an initial matter, this argument is beside the point if only because the district court had multiple grounds for finding Alphapharm's certification and litigation positions baseless, wholly apart from Alphapharm's failure to address the so-called secondary considerations relevant

to an obviousness analysis. *See generally*, Pet. App. 67a-94a. Moreover, Alphapharm's assertion of error in the district court's analysis of commercial success is without basis in law, and is divorced from the record below. *Cf.* APet. 12-13. Alphapharm argued in the district court that it needed discovery to address such "secondary considerations," but the district court noted that an important secondary consideration, namely, the great commercial success of ACTOS®, was of public record and known to Alphapharm (which is why it wanted to copy the drug in the first place). Pet. App. 82a; *see, e.g.*, JA1089-92.[18] In its petition, Alphapharm argues that such considerations present an "affirmative defense" on which the patent holder has the burden of proof. APet. 12 (citing *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006); *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005)). Neither case cited by Alphapharm, nor this Court's decisions, so characterize the role of secondary considerations in an obviousness analysis. *See KSR*, 550 U.S. at 406. On the contrary, Alphapharm's own counsel admitted that "[s]econdary considerations of patentability such as commercial success . . . must be given due consideration . . . ," in reaching a good faith basis for a Paragraph IV certification. JA1580 (citing and relying on *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983)).

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18. Moreover, where, as here, the "marketed product embodies the claimed features, and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus." *Brown & Williamson Tobacco Corp. v. Phillip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000).

CONCLUSION

For the foregoing reasons, the petitions should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

ALPHAPHARM PTY., LTD. and GENPHARM INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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CORPORATE DISCLOSURE STATEMENT

Petitioners set forth its corporate disclosure statement on page *iv* of its Petition for a Writ of Certiorari. There are no amendments to that statement.

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REPLY ARGUMENT

The district court awarded millions of dollars in sanctions against Alphapharm in large measure for deviating from its presuit Notice Letter—routine in Hatch Waxman litigation, and in fact in any civil case under the liberal rules of discovery. Like any other litigant would, Alphapharm buttressed its obviousness allegations using information obtained in the litigation from Takeda. As specifically authorized by statute, Alphapharm timely added prior art to its obviousness case, as that prior art became relevant. *See* 35 U.S.C. § 282. But the district court believed that any such deviation demonstrated sanctionable "bad faith." (Pet. App. A52; Pet. App. A60–61.)[1] Simply put, Alphapharm was deprived of millions of dollars without color of law or due process.

Nothing in Takeda's opposition brief demonstrates to the contrary. Takeda admits that the Federal Circuit specifically noted that deviations in the Notice Letter affected the district court's view of Alphapharm's case. (Opp'n Br. at 17.) Takeda's suggestion that Alphapharm was somehow on notice that it would be subject to sanctions for availing itself of the discovery obtained

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[1] "Pet. App. A__" refers to the appendix accompanying Alphapharm's petition for a writ of certiorari in No. 08–1463. "Pet. App. SA__" refers to the supplemental appendix accompanying Alphapharm's petition for a writ of certiorari in No. 08–1463. "A__" and "JA __" refer to portions of the Confidential Joint Appendix in the Federal Circuit Nos. 07–1269, –1270. "RA__" refers to Petitioners' appendix accompanying this reply brief.

from Takeda lacks merit. No other district court had ever sanctioned a patent challenger for buttressing allegations in the past. The judgment against Alphapharm should be reversed.

I. Alphapharm Fully Preserved its Due Process Claim

Takeda asserts that Alphapharm did not preserve its due process argument because there was no due process issue for the district court or the Federal Circuit to decide. (Opp'n Br. at 27.) Not so. Alphapharm's assertion on the appeal to the Federal Circuit was that it was wrongfully subjected to sanctions for wholly proper litigation conduct. (RA6; RA8–11; *see also*, RA7 ("Alphapharm's obviousness challenge was not 'exceptional' . . . ."); RA7 ("the court erroneously believed that Alphapharm was not entitled to develop its case through discovery."). That sanctions under such circumstances deprive a litigant of due process is this Court's very holding in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), which Alphpharm relied on.

Alphapharm relied on *BMW* because there this Court found that a fact finder's sanction for conduct otherwise lawful deprived a litigant of due process because it "chang[ed] the rules in the middle of the game." (RA14; *see* RA17–20.) Alphapharm consistently made the assertion that sanctions were improper for wholly proper conduct at the district court level (RA3–4), before the Federal Circuit panel (RA8–11; RA13–15),[2]

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[2] Alphapharm explicitly raised the issue using the words "due process" and citing to *BMW* directly—not as Takeda suggests at the rehearing stage of the appeal—but in Alphapharm's *reply brief* to the Federal Circuit. (RA13–15.)

and en banc (RA17–20). Takeda's claim that Alphapharm should have used the words "due process" before the district court strains credulity. (Opp'n Br. at 27) The award of sanctions brought about that very violation. (Pet. App. A28–80.)

This Court and the Federal Circuit have rejected nonpreservation assertions nearly identical to the one Takeda advances here. *Connor v. Finch*, 431 U.S. 407, 421 n.19 (1977) (stating that issues may "appropriately be viewed as an issue implicitly raised by the parties"); *Long Island Sav. Bank, FSB v. United States*, 503 F.3d 1234, 1244 (Fed. Cir. 2007) (although not explicit, "defense 'is inextricably linked to, and is thus 'fairly included' within, the questions presented.'") (citations omitted). To preserve an argument for appeal, "[n]o particular form of words or phrases is essential, but only that the claim of invalidity and the ground therefor be brought to the attention of the [] court with fair precision and in due time. And if the record as a whole shows either expressly or by clear intendment that this was done, the claim is to be regarded as having been adequately presented." *New York ex rel. Bryant v. Zimmerman*, 278 U.S. 63, 66 (1927). This Court should reach the due process issue.

II. Takeda Cannot Defeat Alphapharm's Due Process Claim with Hollow Distinctions Between Punitive and Compensatory Awards

Alphapharm asserted that the district court improperly deprived it of $5.4 million of its property without due process. Takeda can only respond that fee awards under 35 U.S.C. § 285 are not "punishment" but instead are merely "compensatory." (Opp'n Br. at 28-29.) The distinction is a hollow one, and has no support in the language of the Constitution. The Fifth Amendment of the Constitution provides that no person may be "***deprived*** of life, liberty, or property, ***without due process*** of law." U.S. Const. amend. V (emphasis added). The Fifth Amendment does not say that such deprivations are permissible so long as "compensatory."

Nor can Takeda cite to any precedent suggesting that a district court can ignore well-established law and shift millions of dollars in fees to the winner so long as the award is not considered "punishment."[3] With good

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[3] The district court made plain its intent to punish Alphapharm. The district court made repeated references to Alphapharm's bad faith. (Pet. App. A29, A50, A54.) Takeda relies in its papers on those very references (Opp'n Br. at 5–6, 15–18, 28.) And like all punitive awards, the district court expected that its ruling would deter wrongful conduct in the future. *See Exxon Shipping Co. v. Baker*, 128 S.Ct. 2605, 2621 (2008) (punitives are aimed "principally at retribution and deterring harmful conduct"). The court notes that its fees award was in part justified because "[t]here should be no incentive, however, for litigation that is prolonged and complicated by a serious of attacks undertaken without a good faith and without a sound basis in science." (Pet. App. A110.)

reason. The distinction between what is punishment and compensation generally only arises in connection with a defendant's claim in a tort case that the jury's award was excessive. *See Exxon Shipping*, 128 S.Ct. at 2621 (discussing evolution of distinction between punitive and compensatory damages). That was never the basis of Alphapharm's due process claim.

The *BMW* court emphasized that the jury did not have the power to sanction a private litigant for conduct that was otherwise lawful. 517 U.S. at 572–73. The district court did so by punishing Alphapharm in substantial part for deviating from its presuit Notice Letter. The district court below was the first court to do so. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 04–754, 2007 WL 4300155, at *10 (D.N.J. Dec. 5, 2007) (finding that dropping of claims and raising of new ones insufficient evidence of bad faith litigation); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99–8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 6, 2000) (refusing to dismiss affirmative patent defenses not initially plead in presuit notice letter). Tellingly, in the nearly three years since the district court's award of sanctions on this basis, not one other court has chosen to rely on the district court's reasoning. Alphapharm could not have had notice that the use of the confidential documents obtained from Takeda to hone its proofs at trial would subject it to $5.4 million in sanctions.

Takeda's assertions that Alphapharm did have notice that it would be subjected to sanctions are unavailing. Takeda first claims that Alphapharm was aware that Takeda sought sanctions pursuant to § 285. (Opp'n Br. at 29 n.17.) Takeda misses the mark. In its

complaint, Takeda never suggested what specifically about Alphapharm's conduct was exceptional. Moreover, as noted, Alphapharm was quite careful in challenging the '777 patent and did so after securing an opinion of counsel and after the due consideration of three medicinal chemists and a synthetic organic chemist. (JA1650–51.) Dr. Henry Mosberg, independently ratified the scientific basis for Alphapharm's obviousness position at trial. (A1828–32, ¶¶17–23.) But the court ignored such clear evidence of Alphapharm's good faith as a result of its mistaken belief that any deviation from a presuit Notice Letter demonstrated bad faith.[4] (A81; JA30) (commenting that Alphapharm should have limited itself to the "theories presented in [its Notice Letter]".)

Takeda next tries to defend the district court's decision to sanction Alphapharm for adding prior-art references prior to trial—permissible under 35 U.S.C. § 282—by noting that district courts may time their own discovery. (*See* Opp'n Br. at 29, n.16.) But the district court never required Alphapharm to serve notice of its

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[4] Takeda makes much of the district court's belief that the deposition testimony of Alphapharm's witnesses demonstrated its bad faith. (Opp'n Br. at 13–14.) But this testimony was taken out of context. For example, the district court believed that Alphapharm's Dr. Rosenberg selected the prior-art compound b because it was "similar to pioglitazone" but ignored those portions of his deposition where he noted that the skilled artisan would select that compound because of its very high efficacy. (A2224, 169:10–16.) The court never heard from Alphapharm's witnesses at trial, and so its findings are not entitled to any special deference. *See* Fed. R. Civ. P. 52(a) (granting district court deference to credibility findings of witnesses before it).

prior-art references earlier than required under § 282. And in any event, Takeda knew months in advance of trial that Alphapharm would rely on these references. Alphapharm's 30(b)(6) witnesses, Dr. Howard Rosenberg and Barry Spencer, specifically relied on the references during their deposition testimony to demonstrate the obviousness of the '777 patent. (RA22–23; RA25.) And Alphapharm's medicinal chemistry expert Dr. Mosberg relied on these references in his expert report and trial declaration, served 6 months before trial. (RA2–3; A1828–33, ¶¶17–27.) Under § 282, a defendant need only serve notice of additional prior-art references he intends to rely on one month in advance of trial. Although Alphapharm fully complied with the statute, it was sanctioned anyway. (Pet. App. A61) ("To the extent that the '605 and '779 patent provided any support for the selection of compound (b) as a lead compound, then Alphapharm was under an obligation to identify these two references in its [Notice Letter].").

III. The District Court's Commercial Success "Analysis" Was Infected Throughout by Legal Error

As noted in the Petition, the district court also improperly sanctioned Alphapharm for failing to address ***the patentee's*** affirmative defense of "commercial success," one of the so-called "secondary indicia of nonobviousness." (Pet. for Writ of Cert. at 12–13.) Takeda responds simply by noting that the commercial success of Takeda's Actos® product motivated its filing. (Opp'n Br. at 30–31.) Its response makes little sense. A secondary consideration of

nonobviousness allows a court to use criteria other than the hypothetical person of skill in the art referenced in 35 U.S.C. § 103 to analyze the question of obviousness. *See Graham v. John Deere*, 383 U.S. 1, 17–18 (1996). The secondary indicia are an analytical rubric, not as Takeda led the district court to believe, a simple "checklist." For example, the district court apparently believed—on the basis of Alphapharm's possession of presuit sales data—that the "commercial success of Actos® was well-known to Alphapharm . . . ." (Pet. App. A50.) But sales data alone is insufficient to warrant any inference of commercial success. *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

The analysis of obviousness using the secondary indicia of commercial success is much more involved than the district court appeared to appreciate. The utility of commercial success as objective evidence rests on four fundamental inferences. According to Professor Edmund Kitch in his now-classic article on the subject, these inferences are as follows:

> First, that the commercial success is due to the invention. Second, that if an improvement has in fact become commercially successful, it is likely that this potential commercial success was perceived before its development. Third, the potential commercial success having been perceived, it is likely that efforts were made to develop the improvement. Fourth, the efforts having been made by men of skill in the art, they failed because the patentee was the first to reduce his development to practice.

Edmund Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 *Sup. Ct. Rev.* 293, 332 (1966). Appellate courts frequently rely on Kitch's analysis. *See, e.g., Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1346 (7th Cir. 1983); *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 541 n.5 (3d Cir. 1981); *Eli Lilly & Co. v. Premo Pharms. Labs., Inc.*, 630 F.2d 120, 126 (3d Cir. 1980); *Nat'l Filters, Inc. v. Research Prods. Corp.*, 384 F.2d 516, 520 (5th Cir. 1967).

Thus, a corporation cannot simply put on evidence at trial of impressive sales figures or market share data and baldly assert that the claims of its patent are not obvious as a result. There must be some link—some nexus—demonstrating that the merits of the invention over the prior art were responsible for the later success. In *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed. Cir. 1985), for example, the inventor of a holding arm for automatic graphic chart pens introduced evidence of substantial commercial success. The patent challenger countered with evidence that the success was attributable to ***nonpatent*** features, specifically: (1) the patentee's established market leadership; (2) advertising and promotion; and (3) other unpatented features of the pen. *Id.* at 316. In rejecting the patentee's claim that commercial success demonstrated nonobviousness, the court noted: "[I]t cannot be said that the commercial success here may not have been due in large part to other economic and commercial factors unrelated to the technical quality of the patented subject matter." *Id.* The district court ignored Alphapharm's evidence at trial demonstrating that non-patented features, including market forces, an aggressive advertising campaign and unusual giveaways accounted for the qualified success of Actos®. (Pet. App. SA1–48.)

But more importantly, the district court believed that Alphapharm was under a duty to rebut[5] in the Notice Letter—what it could not possibly address intelligently—let alone rebut. (Pet. App. A49–50.) In order to demonstrate that Takeda's claims of huge sales had to do with factors other than its patented features, Alphapharm needed discovery of information all pharmaceutical companies maintain as confidential: Takeda's market position, its advertising and marketing budget, and per-product profit margins. None of this data became available until ***after*** Alphapharm drafted its Notice Letter. Takeda does not maintain otherwise in its opposition brief. Nor could Alphapharm have foreseen that the failure to address this defense would have resulted in sanctions. No other district court in the country had so held. Nor has any court since.

Takeda strangely asserts that secondary considerations of obviousness are not affirmative defenses on which the patentee has the burden of proof, but instead elements of a challenger's proof. (Opp'n Br. at 31.) That was not Takeda's position at the trial below.

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[5] Takeda claims as the district court that where the "marketed product embodies the claimed features," a nexus is presumed. (Opp'n Br. at 31 n.18.) But Takeda proves too much. If Takeda's claim were correct, a patent challenger such as Alphapharm could never rebut the presumption and thus could never challenge the patent on a pretrial basis. Many patents covering products that are extensively marketed and arguably "successful" would thus be rendered immune from challenge. Such a result is hardly consistent with Congress' purpose in enacting of the Hatch-Waxman Act—to "make lower cost generic drugs available more quickly." *See* H.R. Rep. No. 108–81, at 9 (2003).

Then, Takeda argued in its pretrial brief to the district court that there was no need to address the considerations if Alphapharm failed to meet its burden to show prima facie obviousness. (*See* RA27) ("Without Alphapharm having proved a *prima facie* case of obviousness, there is no need for this Court to consider objective evidence of non-obviousness.".) The district court agreed. *See* (A92) ("Given Alphapharm's failure to show prima facie obviousness, there is no need for an extended discussion of the objective factors used to evaluate obviousness.".) Takeda and the district court's earlier analysis make little sense only if secondary considerations were a means ***for the patentee*** to alternatively demonstrate the nonobviousness of a patent in the face of a prima facie case of obviousness.

And despite Takeda's weak suggestion to the contrary (Opp'n Br. at 31), the Federal Circuit has long treated secondary indicia as an affirmative defense by the patentee to an obviousness challenge.[6] As the Federal Circuit noted in *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996), "[o]nce a *prima facie* case of obviousness has been established, the burden shifts to the applicant to come forward with evidence of nonobviousness to overcome the *prima facie* case." *Accord In re Beattie*, 974 F.2d 1309, 1313 (Fed. Cir. 1992)

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[6] This Court has not yet opined on either the evidentiary significance or who bears the burden of secondary considerations. The *Graham* Court only noted for example that such considerations "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." 383 U.S. at 17–18. *See also KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 400 (2007) (citing the same language).

(secondary indicia "may be sufficient to overcome a prima facie case of obviousness."). *See also SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1358 (Fed. Cir. 2000) ("[T]he mere existence of . . . licenses [i.e., secondary considerations] is insufficient to overcome the conclusion of obviousness, as based on the express teachings in the prior art that would have motivated one of ordinary skill to modify . . . cells to be used with unknown compounds."). Thus, the district court's assumption that commercial success should have been addressed in Alphapharm's Notice Letter was simply mistaken. Notably, the Federal Circuit chose not to address this error. (Pet. App. A1–26.)

CONCLUSION

Alphapharm respectfully requests that this Court grant the petition for a writ of certiorari, and reverse the judgment of the Federal Circuit.

Respectfully submitted,

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August 11, 2009

APPENDIX A — EXCERPTED ALPHAPHARM'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' REQUEST FOR ATTORNEYS' FEES DATED APRIL 28, 2006

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No.
03 CV 8253 (DLC)

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,

Plaintiffs,

v.

Mylan Laboratories, Inc.,
Mylan Pharmaceuticals, Inc., and
UDL Laboratories, Inc.,

Defendants.

Civil Action No.
04 CV 1966 (DLC)

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,

Plaintiffs,

v.

Alphapharm Pty. Ltd., and Genpharm, Inc.,

Defendants.

Appendix A

ALPHAPHARM'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' REQUEST FOR ATTORNEYS' FEES

* * *

Next, Alphapharm respectfully directs the court to a very important opinion espoused by Dr. Mosberg. Dr. Mosberg believed that the skilled artisan would have had a reasonable expectation of successfully obtaining a better drug—not necessarily a blockbuster drug (something the law does not require)—through the routine optimization steps of "ring-walking" and homologation. Dr. Mosberg told Alphapharm his opinion. He expressed it in his expert report. And he testified about it in his trial declaration.

Opinion

> The skilled artisan could reasonably expect success in achieving a better drug through the optimization steps of ring walking and homologation.

Expert Report

> "[Ring walking or] variation in substituent position is routine in drug discovery, since such changes often lead to improvements."[50]

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50. Ex. U, 7/15/05 Mosberg Ex. Rpt. at 11.

"'[H]omologation' [ ] is a standard approach in drug design, especially when attempting to 'fine tune' a successful lead compound, since small structural changes often result in significant efficacy improvements."[51]

Trial Declaration

"One skilled in the art of medicinal chemistry would have been motivated to 'tweak' the 6 methyl to maximize its effectiveness by altering the position of the methyl on the pyridyl ring ('walking the methyl around the ring') and by substituting an ethyl (C_2H_5) for the methyl in the available positions on the pyridyl ring . . . **Though there is no absolute predictability in the field of medicinal chemistry**, any person of ordinary skill in the art would have had a ***reasonable expectation of success*** in 'tweaking' the lead compound in this way."[52]

* * *

A. Alphapharm Used the Discovery Process to Hone the Positions Advanced in the Notice

Alphapharm used the discovery process to: 1) support its theories of invalidity, and 2) rebut

51. *Id.* at 12.

52. Ex. C 11/18/05 Trial Decl., at ¶29.

Takeda's. Alphapharm never used discovery to "fish" around for new theories. During expert discovery, for example, Alphapharm determined that the failure of Takeda to reveal the '605 and '779 patents would have had a substantial impact on the Examiner, because the prior art had not "taught away" from the six-methyl. In fact, Takeda specifically claimed that compound after Sohda II published.[56] And Takeda noted that the six-methyl had become ***especially important*** in the file history.[57] Any reasonable litigant would have made same arguments. ***Prior art must be viewed as a whole.*** *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (references must be viewed as a whole and not in isolation of one another). It would have been negligent for Alphapharm's counsel to ignore these references once Takeda adopted the position that Sohda II "taught away" from compound 58.

* * * *

56. Ex. M at claim 4.

57. Ex. P, '779 file history, July 7, 1982 Preliminary Amendment, alpha-54 (emphasis added).

APPENDIX B — EXCERPTED CORRECTED BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. AND GENPHARM, INC. DATED FEBRUARY 11, 2008

Appeal Nos. 07-1269, -1270

United States Court of Appeals

for the

Federal Circuit

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs-Appellees,

– v. –

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC. and UDL LABORATORIES, INC.,

Defendants-Appellants,

– and –

ALPHAPHARM PTY., LTD. and GENPHARM, INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CASE NO. 04-CIV-1966, JUDGE DENISE COTE

CORRECTED BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. and GENPHARM, INC.

Appendix B

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* * *

3. The purpose of a Paragraph IV Letter is to provide the patent holder sufficient information to assess whether or not to sue the ANDA applicant. The law does not require the Paragraph IV Letter to contain each and every argument the patent challenger will use at trial. The district court found that Alphapharm committed litigation misconduct because it made arguments, and relied on prior-art references, outside the scope of those presented in its Paragraph IV Letter. Did the district court clearly err?

* * *

Appendix B

SUMMARY OF THE ARGUMENT

Alphapharm's obviousness challenge was not "exceptional" within the meaning of § 285. It was well-founded. The compounds Takeda claimed in the '777 patent reflected nothing more than routine innovation in Alphapharm's view. Takeda made simple substitutions to the most-potent compound in the prior art to reduce that compound's side-effect profile. In good faith, Alphapharm determined that any skilled artisan would have had every reason to make—and could have made—those routine changes. The district court thought otherwise, and found the compounds claimed in the '777 patent nonobvious. But Alphapharm's failure to convince the district court by clear and convincing evidence does not convert Alphapharm into a bad-faith litigant.

A number of factors—none justified by the record—led the court to assess fees against Alphapharm. Firstly, the district court lowered the bar for an exceptional-case finding. Rather than requiring Takeda to prove Alphapharm's challenge to the '777 patent presented a gross injustice by clear and convincing evidence, the district court only required a showing of simple negligence. Secondly, the district court misapplied the law of structural obviousness in assessing Alphapharm's good-faith challenge to the claimed compounds. Thirdly, the court erroneously believed that Alphapharm was not entitled to develop its case through discovery. Under that view, any deviation at trial from the allegations presented in Alphapharm's presuit Paragraph IV Letter amounted to a "course shift" and a "search for

obviousness." Finally, the district court appears to have misinterpreted deposition testimony concerning Alphapharm's initial investigation and assumed that Alphapharm arbitrarily granted itself a bifurcation of the attorneys' fees issues. These and other errors converted a routine challenge based on structural obviousness into something sinister in the court's view. The exceptional-case finding must be reversed and the award of attorneys' and expert fees vacated.

ARGUMENT

* * *

B. In Direct Conflict with the Hatch-Waxman Act, the District Court Required Alphapharm to Disclose Every Trial Argument in Its Paragraph IV Letter

In addition to the separate error of requiring Alphapharm to identify compound b as a lead compound, the district court faulted Alphapharm for not identifying each and every reference it later relied on at trial. (JA56; JA59-60; JA70.)

But courts have directly addressed and rejected any requirement that generic drug companies be limited at trial to the content of their Paragraph IV Letters. *See e.g., Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 04-754, 2007 WL 4300155, at *7-11 (D.N.J. Dec. 5, 2007) (rejecting Pfizer's argument that Teva's Paragraph IV Letter was submitted in bad faith for failing to identify

prior-art references relied on at trial). The Paragraph IV Letter need only alert the patentee to the possibility of infringement by the ANDA applicant so that "patent owner can protect its interests in its patents by filing a patent-infringement action." *See Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99-8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 6, 2000). Here, Alphapharm complied with its statutory requirements and the district court appeared to agree. (JA51.)

Nonetheless, the district court still found Alphapharm's Paragraph IV Letter baseless. Its ruling would have the effect of frustrating the very purposes of the Hatch-Waxman Act, which as demonstrated from its legislative history, was to reduce health-care costs by encouraging early challenges to invalid or unenforceable patents. In 1997, reflecting on the 13-year history of the Act, Senator Hatch noted the Act "continues to provide incentives for drug companies to undertake research on new drugs while enabling low cost, generic equivalents that are relied upon by consumers ***to come quickly to the market***." S. Rep. No. 105-36(I), at 125 (1997) (emphasis added). The House seconded Senator Hatch's sentiment. *See* H.R. Rep. No. 108-181, at 9 (2003) (noting that Title XI, Access to Affordable Pharmaceuticals, "[i]ncorporates text of S. 1225 as adopted by the Senate, which will make lower cost generic drugs available more quickly.").

The district court's decision, if left to stand, would limit ANDA filers to presuit Paragraph IV Letters and would frustrate the incentives to early challenges the

Act envisioned. Generic companies would refrain from attacking invalid patents unless confident the case could be won without pretrial discovery. But ANDA cases are no different from other cases in the federal system. Parties must be afforded a reasonable time to develop facts and refine legal theories. *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) (holding that infringement inquiry not limited to ANDA alone but to other materials challenger submitted to the FDA "and other pertinent evidence provided by the parties"); *Dey, L.P. v. Ivax Pharms., Inc.*, 233 F.R.D. 567, 570 (C.D. Cal. 2005) (holding in ANDA case that discovery entitled defendants to narrow and clarify patentee's position on inventorship). There is no basis in the Hatch-Waxman Act or the caselaw to carve out an exception for ANDA cases.

Indeed, it is axiomatic that positions develop and change during the course of patent litigation, particularly during fact and expert discovery. For example, the district court's ruling would render § 282, which requires a defendant to identify the prior art it intends to rely on ***30 days before trial,*** meaningless. 35 U.S.C. § 282. It would also discourage ANDA applicants from availing themselves of the Federal Rules of Civil Procedure because ANDA applicants would risk attorneys' fees when moving to amend or supplement their pleadings. *See* Fed. R. Civ. P. 15.

Further, allegations of unenforceability are commonly raised ***after*** considerable discovery has been accomplished such that a party can meet the obligations

under Federal Rules of Civil Procedure 9 and 11. To require an ANDA applicant, under penalty of an attorneys' fees sanction, to include every noninfringement, invalidity, and unenforceability argument in a presuit Paragraph IV Letter could never be the law, as this Court has already recognized. *See Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1304 (Fed. Cir. 2004) (finding case not exceptional despite that patentee changed its infringement theory in the middle of discovery); *see also Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 409 F. Supp. 2d 722, 728 n.2 (E.D. Va. 2006) (noting that every ANDA filing is essentially "baseless" when the challenger ultimately loses at trial). The district court's ruling turns "exceptional" on its head.

* * * *

APPENDIX C — EXCERPTED CORRECTED REPLY BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. AND GENPHARM, INC. DATED JUNE 26, 2008

Appeal Nos. 07-1269, -1270

United States Court of Appeals

for the

Federal Circuit

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs-Appellees,

– v. –

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC. and UDL LABORATORIES, INC.,

Defendants-Appellants,

– and –

ALPHAPHARM PTY., LTD. and GENPHARM, INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CASE NO. 04-CIV-1966, JUDGE DENISE COTE

CORRECTED REPLY BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. and GENPHARM, INC.

Appendix C

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June 26, 2008

* * *

TABLE OF AUTHORITIES

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BMW of N. Am. v. Gore,
517 U.S. 559 (1996) 14

* * *

Indeed, in patent cases, the use of additional prior-art references—and additional theories developed with those references—is expected. As Alphapharm pointed out in the opening brief, the challenger must alert the patentee to ***all*** prior-art references it wil rely on—not at the outset of a case—but within 30 days of trial. *See* 35 U.S.C. § 282. Takeda does not—and cannot—

maintain that a special exception to this provision exists for Hatch-Waxman cases. Yet, the district court sanctioned Alphapharm for its later timely reliance on prior-art references such as U.S. Patents 4,340,605 and 4,444,779.[2] (JA62-63.) Doing so amounts to little more than changing the rules in the middle of the game. *C.f., BMW of N. Am. v. Gore*, 517 U.S. 559, 573 (1996) (prohibiting Alabama jury from imposing punitive sanctions on conduct lawful in other jurisdictions).

* * *

The ruling will also create perverse incentives. The district court chose to sanction Alphapharm for dropping a theory based on what it had learned in discovery (JA57-58)—the very outcome Takeda urged upon the district court in the first instance. (JA175; JA181-82; JA2020-22.) Affirming that ruling will only encourage generic challengers to put in and maintain every possible argument at trial, for fear that narrowing the issues will be used against them in a later fees application.

Nowhere in its Opposition does Takeda address these profound implications, and its silence is deafening. Left to stand, the court's ruling arms the brand-name company with the full use of the broad discovery set forth in the Federal Rules of Civil Procedure while

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2. Alphapharm's § 282 Statement with these references was served on December 15, 2005, more than 30 days before the trial began on January 17, 2006. (A9549-53.)

forcing a generic company to subject itself to sanctions for availing itself of the same Rules. Such a result is clearly contrary to this Court's law. "[T]here is and should be no difference in the standards applicable to patentees and infringers who engage in bad faith litigation." *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 811 (Fed. Cir. 1990). Reversing the district court's ruling will restore a level playing ground. *See Doubleday & Co. v. Curtis*, 763 F.2d 495, 503 (2d Cir. 1985) (reversing dismissal of claim where dismissal "violated the spirit of both the United States Constitution [due process clause] and the Federal Rules of Civil Procedure [Rule 8(c)].").

* * * *

APPENDIX D — EXCERPTED PETITION FOR REHEARING EN BANC FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. AND GENPHARM, INC. DATED DECEMBER 22, 2008

Appeal Nos. 07-1269, -1270

United States Court of Appeals

for the

Federal Circuit

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs-Appellees,

– v. –

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC. and UDL LABORATORIES, INC.,

Defendants-Appellants,

– and –

ALPHAPHARM PTY., LTD. and GENPHARM, INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CASE NO. 04-CIV-1966, JUDGE DENISE COTE

PETITION FOR REHEARING EN BANC FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. and GENPHARM, INC.

Appendix D

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December 22, 2008

STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is at least contrary to the following decisions of this Court: *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995) and *State Industries, Inc., v. A.O. Smith Corp.*, 751 F.2d 1226, 1238 (Fed. Cir. 1985). The panel decision also renders nugatory 35 U.S.C. § 282 and Rules 26 through 37 of the Federal Rules of Civil Procedure for patent challengers. More broadly, the panel's affirmance violates Alphapharm's right to due process. U.S. Const., amend. V; *BMW of N. Am. v. Gore*, 517 U.S. 559, 573 (1996).

If the panel decision is left to stand as it is, it will turn Hatch-Waxman litigation on its head and disturb

the delicate balance Congress intended between the brand and generic drug industries. This appeal therefore requires an answer to one or more precedent-setting questions of exceptional importance:

1. May a court properly sanction a patent challenger who relies on prior art whose relevance was first timely revealed in discovery and admitted into evidence by the district court?

2. In a Hatch-Waxman case, must a patent challenger in a presuit notice provide not only a detailed basis that a patent is invalid, but also address potential affirmative defenses such as lack of commercial success?

Dated: December 22, 2008

By: Kevin Murphy, Esq.
Attorney of Record for
Defendants-Appellants
Alphapharm Pty., Ltd. & Genpharm Inc.

I. POINTS OF LAW AND POLICY IGNORED BY THE PANEL

A. The Panel's Errors

Alphapharm petitions for rehearing en banc of the panel decision affirming the district court's award of attorney and expert fees in the amount of $5.4 million against Alphapharm. The affirmance profoundly

changes the law of this Circuit and shifts the balance Congress carefully crafted between a generic challenger and a brand patentee in a Hatch-Waxman case-to the benefit of the patentee. The affirmance cannot and should not go undisturbed.

Specifically, the district court found that Alphapharm"s pre-litigation statutory Notice of Certification Letter (the "Notice") was baseless and further found Alphapharm to have committed litigation misconduct, concluding that Alphapharm should have "simply pursued the theories presented in" its Notice. (JA30.) This has never been the law. *See, e.g., Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No 04-754, 2007 WL 4300155, at *7-11 (D.N.J. Dec. 5, 2007) (rejecting notion that a notice letter was submitted in bad faith for failing to identify all prior-art references relied on at trial). A case is not suddenly "exceptional" because a party relies on discovery to support its invalidity defense at trial. The award amounts to a changing of the rules in the middle of the game, and violates Alphapharm's right to due process. *Cf. BMW of N. Am.*, 517 U.S. 573 at 573 (prohibiting Alabama jury from imposing punitive sanctions on conduct lawful in other jurisdictions).

The panel appeared to take no position on the district court's clear error, noting that the district court did not "fault [] Alphapharm ***simply*** for changing its obviousness argument at trial from the theory advanced in the Paragraph IV letter." Slip Op. at 8 (emphasis added). Moreover, because the district court never specified what it was about Alphapharm's conduct that

defiled the "temple of justice", the panel ignored the standard in *Amsted Indus. v. Buckeye Steel Castings Co.*, 23 F.3d 374, 378 (Fed. Cir. 1994), in upholding the award of expert fees. The panel had a duty to vacate an exceptional-case finding when that finding rests on ***any*** legally improper grounds. *See Molins*, 48 F.3d at 1186 (remanding for additional findings after accepting as proper some but not all grounds for exceptional-case-finding). Exceptional-case findings must "not [] be an ordinary thing." *State Indus.*, 751 F.2d at 1238 (reversing award of attorneys' fees).

* * * *

APPENDIX E — EXCERPTED DEPOSITION OF HOWARD ROSENBERG DATED MARCH 30, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 04-cv-1966
(DLC)

TAKEDA CHEMICAL INDUSTRIES, LTD., and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

vs.

ALPHAPHARM PTY, LTD., and GENPHARM, INC.,

Defendants.

Confidential – Attorneys' Eyes Only

March 30, 2005

9:01 a.m.

Continued deposition of HOWARD ROSENBERG, held at the offices of Edwards & Angell, 750 Lexington Avenue, New York, New York, before Laurie A. Collins, a Registered Professional Reporter and Notary Public of the State of New York.

Appendix E

[245] * * *

Q. Do you agree or disagree that of the compounds which had been disclosed prior to the filing of the application for the '777 patent the compound shown at the bottom of page 1 of the information disclosure statement is the compound which bears the closest structural similarity to pioglitazone?

MR. MURPHY: Objection.

A. I can't agree with that a hundred percent because the prior art shows simple pyridine as well, and I would include those as well as this particular compound as closest prior art.

Q. When you say "simple pyridine," do I understand you correctly to mean unsubstituted pyridine?

[246] A. In the prior art as I understand it, there was an example of a simple pyridine with no substitution. But there was also claims to a pyridine with substitution, although not exemplified.

Q. What prior art were you referencing in your prior answer?

A. As I understand it, the other patents that resulted out of the '200 patent.

Q. What patents were those?

A. I think it's the '605 patent I need to check it.

Q. Is it your understanding that what you've referred to as the '605 patent is a Takeda patent?

A. I think so.

Q. And do you know when that patent issued?

A. I think — unless you show me, I can't give you a date. But I understand it's a division of the '200. There were two sevens patents that came out, if I remember rightly — I can't remember, but maybe '779 — and shows the compound at the bottom of the page here we're referring to. [247] I have the impression the other patent, '605, has claimed the straight pyridine but in the first claim includes — it generalizes alkyl substitution but does not exemplify.

* * * *

APPENDIX F — EXCERPTED DEPOSITION OF BARRY SPENCER DATED MAY 5, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CONFIDENTIAL

No. 04-cv-1966
(DLC)

TAKEDA CHEMICAL INDUSTRIES, LTD., and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

vs.

ALPHAPHARM PTY, LTD., and GENPHARM, INC.,

Defendants.

May 5, 2005

9:47 a.m.

Deposition of BARRY SPENCER, held at the offices of Edwards & Angell, 750 Lexington Avenue, New York, New York, pursuant to Rule 30 (b) (6) before Laurie A. Collins, a Registered Professional Reporter and Notary Public of the State of New York.

Appendix F

* * *

[36] Q. 71. My mistake.

Let me ask you, is there any basis upon which defendants or any of them contend or will contend that the '777 patent is invalid, unenforceable or will not be infringed which is not contained in Exhibit 15?

A. What I would like to add, what Alphapharm would like to add, is that in — as [37] part of the review of the prior art specifically the Sohda article 1982 and the '200 patent and the file history thereof and the '777 file history or prosecution history, basically in looking at these — If I can give just a bit of a run-through.

* * * *

APPENDIX G — EXCERPTED PLAINTIFFS' OPENING PRE-TRIAL MEMORANDUM OF LAW AND COMBINED PRE-TRIAL SUBMISSIONS WITH RESPECT TO THE '777 PATENT DATED NOVEMBER 18, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 03 CV 8250 (DLC)
03 CV 8253 (DLC)
03 CV 8254 (DLC)
04 CV 1966 (DLC)
(Consolidated for trial)

Honorable Denise L. Cote

Takeda Chemical Industries, Ltd., and Takeda Pharmaceuticals North America, Inc.,

Plaintiffs,

v.

Ranbaxy Laboratories, Ltd., et al.,
Mylan Laboratories, Inc., et al.,
Watson Pharmaceuticals, Inc., et al.,
Alphapharm Pty, Ltd., et al.,

Defendants.

PLAINTIFFS' OPENING PRE-TRIAL MEMORANDUM OF LAW AND COMBINED PRE-TRIAL SUBMISSIONS WITH RESPECT TO THE '777 PATENT

Appendix G

* * *

IV. SECONDARY CONSIDERATIONS ALSO DEMONSTRATE NON-OBVIOUSNESS

Without Alphapharm having proved a prima facie case of obviousness, there is no need for this Court to consider objective evidence of non-obviousness. Nevertheless, were that evidence considered, it would strongly overcome any such prima facie case and establish non-obviousness. The so-called "secondary considerations" include: (1) the extent of commercial success of the patented invention; (2) unexpected properties of the invention compared to the "closest" prior art; (3) whether the invention satisfies a long-felt need; (4) whether others have failed to find a solution to the problem solved by the invention; and (5) copying of the invention by others. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). Skepticism by those skilled in the art, and industrial acclaim, are also factors. Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH, 139 F.3d 877, 855 (Fed. Cir. 1998) (skepticism); Heidelberg Harris v. Mitsubishi Heavy Indus. Ltd., Nos. 99-1100, 99-1101, 99-1102, 2000 WL 1375270, at 11 (Fed. Cir. Sept. 18, 2000) (industrial acclaim). Although Takeda bears the burden of coming forward with rebuttal evidence showing facts supporting non-obviousness, it remains Alphapharm's burden to prove by clear and convincing evidence that these objective factors point to obviousness.

* * * *

Supreme Court, U.S.
FILED
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(3) (2)

Nos. 08-1461 & 08-1463

IN THE

Supreme Court of the United States

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., & UDL LABORATORIES, INC.,

Petitioners,

&

ALPHAPHARM PTY., LTD. & GENPHARM INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUSTRIES, LTD. & TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONERS

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U.S. Dept. of Health and Human Services, About FDA: What We Do 4

INTEREST OF *AMICUS CURIAE*[1]

Founded in 2001, the Generic Pharmaceutical Association (GPhA) is a trade association devoted to making lower priced, high quality generic drugs available to patients and providers, thus assisting in the battle against rapidly growing healthcare costs. Its members include manufacturers and distributors of finished generic drug products and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry.

Generic drugs play an essential role in reducing consumer drug costs, especially for older Americans, who consume more healthcare products and services than any other age group.[2] In 2008 alone, average prices for the 185 generic drugs most widely used by Medicare beneficiaries fell by 10.6 percent, contrasted with an 8.7 percent increase in average prices for the 219 most

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[1] No counsel for a party authored this brief in whole or in part, and no counsel for a party or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. Counsel of record for all parties received notice at least 10 days prior to the due date of the *amicus curiae*'s intention to file this brief. All parties have consented to the filing of this brief.

[2] *See* Federal Interagency Forum on Aging-Related Statistics, *Older Americans 2008: Key Indicators of Well-Being* 50 (2008), *available at* http://www.agingstats.gov/agingstatsdotnet/Main_Site/Data/2008_Documents/Health_Care.pdf.

widely used branded prescription drugs.[3] The combination of rising costs of branded prescription drugs, unprecedented rates of unemployment, and declining values of housing and investment creates an even greater need to accelerate access to generic drugs—particularly when consumers have less discretionary income for medical care.

The GPhA has a strong interest in preserving and strengthening incentives for manufacturers to move generic drugs based on abbreviated new drug applications into the hands of the American public as quickly as possible, consistent with the legitimate patent rights of branded drug companies. Specifically, the GPhA has a critical interest in ensuring proper application of the patent laws and the system created by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA).

SUMMARY OF ARGUMENT

The Federal Circuit's failure to address the district court's misapplication of the law and lopsided focus on the Petitioners' abbreviated new drug application (ANDA) certifications in this case is at odds with the intent of the Hatch-Waxman Act and the Federal Rules of Civil Procedure. The unique mechanism Congress created by the Hatch-Waxman Act permits an ANDA applicant to submit an ANDA to the FDA with a

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[3] AARP Public Policy Institute, *Rx Watchdog Report. Trends in Manufacturer Prices of Prescription Drugs Used by Medicare Beneficiaries 2008 Year-End Update* vi, viii (2008), *available at* http://assets.aarp.org/rgcenter/health/2009_07_rxq408.pdf.

certification that "to the best of [its] knowledge" the patents ostensibly associated with a particular drug are invalid or not infringed. That certification is based solely on publicly available information. The purpose of the ANDA approval process is to evaluate the safety and efficacy of the drug for consumers. The FDA uses the information in the ANDA to assess ingredients, labeling, packaging, and dosage requirements. The FDA does not make any determination regarding invalidity or non-infringement of any asserted patent claims.

Rather, Congress provided that all disputes regarding infringement of ANDA-related patents would be resolved in the federal courts. Congress achieved this by designating the filing of an ANDA, which occurs before any products are actually sold, a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). By creating a case or controversy in the form of an infringement claim by the patentee against the ANDA applicant as a prerequisite to bringing the generic drug to market, Congress surely intended that the litigants in Hatch-Waxman cases would also receive the benefit of fact discovery, notice pleading, liberal amendment of pleadings, and all other provisions of the Federal Rules of Civil Procedure.

The Federal Circuit's ruling sends a chilling message to the generic drug industry that in order to avoid a finding of "exceptionality" and an award of fees, an ANDA applicant may only allege at trial the exact defenses as presented in its pre-litigation ANDA certification rather than pursue defenses that conform to the evidence developed through discovery and presented at trial. Because this result is contrary to the Federal Rules of Civil Procedure and the policy

objectives of the Hatch-Waxman Act, this Court should grant the petitions and reverse the Federal Circuit's decision.

ARGUMENT

A. The Hatch-Waxman Act Establishes an Administrative ANDA Approval Process and a Patent Litigation Procedure that Address Separate Policy Interests.

The animating policy underlying the Hatch-Waxman amendments to the patent and drug laws is "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991); H.R. Rep. No. 98-857, pt. 1, at 14 (1984). To achieve that goal, Hatch-Waxman created an administrative ANDA approval process and a means for allowing patent owners to resolve legitimate claims related to ANDA products in litigation before the products are made and marketed. Although the ANDA approval process and patent litigation components of Hatch-Waxman interrelate in important ways, they are distinct procedures deliberately established by Congress to address separate policy interests.

On one hand, the ANDA approval process is an administrative procedure in the FDA designed to speed innovations that make drugs more effective, safer, and more affordable while protecting the public health by assuring the safety, efficacy, and security of those drugs. *See* U.S. Dept. of Health and Human Services, About FDA: What We Do, http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited June 29, 2009).

The principal goal of the FDA's approval process is to assess whether the ANDA drug is bioequivalent to the branded drug, whether the information provided supports the applicant's claim that the active ingredients, dosages, and labeling are identical to those in the branded drug, and whether the methods that will be used in the manufacture and packaging of the ANDA drug are adequate to ensure its quality and purity. *See* 21 C.F.R. § 314.127.

As part of this procedure, all ANDAs must include a certification made "in the opinion of the applicant and to the best of his knowledge" regarding patents listed in the Orange Book as possibly claiming the product described in the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii). The certification, as part of the ANDA, is made *to the FDA*. *Id.* Where the certification states the patent is believed to be invalid or not infringed, the applicant must provide *notice* of the certification *to the patent owner*, together with a detailed statement of the basis of the applicant's opinion. *Id.* § 355(j)(2)(B). The patent owner may or may not initiate litigation based on the notice, but the ANDA approval process will begin nonetheless and the FDA will evaluate the ANDA.

On the other hand, the patent litigation component of Hatch-Waxman was designed as "a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator's drugs" in the federal courts before the generic drug has been marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003). To create this mechanism, Congress amended the patent laws to deem the filing of an ANDA a "highly artificial" act of patent infringement, giving

the federal courts subject matter jurisdiction to adjudicate claims. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Warner-Lambert*, 316 F.3d at 1365 (noting that filing an ANDA is "an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product"). Distinct from the FDA's ANDA approval process, any civil complaint filed by the patent owner activates an ordinary patent infringement case. 35 U.S.C. § 271(e)(2).

The only relationship between the FDA's administrative process and the civil litigation is the timing of the final approval of the ANDA. If the patent owner initiated litigation within forty-five days of receiving the notice letter, the FDA may not approve the ANDA for thirty months. *Id.* § 355(j)(5)(B). If the court finds the patent to be invalid or not infringed before the end of the thirty-month stay, the FDA's approval is made effective as of the date of the court's decision. *Id.* § 355(j)(5)(B)(iii)(I). If, however, the thirty-month stay expires prior to the district court's ruling, the FDA may approve the ANDA before a decision is issued. *See* Federal Trade Commission, *Generic Drug Entry: Prior to Patent Expiration: An FTC Study* 22 & n.20 (2008), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (noting in a 2002 study that the FDA approved ANDAs in eight out of twenty-two ANDA patent infringement cases after the thirty-month stay had expired and prior to a final decision in pending litigation).

Accordingly, although the FDA's administrative procedure and the patent infringement litigation both flow from the ANDA, they serve separate purposes. Approval for market entry involves a separate analysis from the questions of validity and infringement reviewed by either the Patent and Trademark Office or a district court. The patent certification included in the ANDA indicates the applicant's opinion that the generic drug is bioequivalent to the branded drug, is non-infringing, and should therefore be quickly approved and made available to consumers as a more affordable alternative. The FDA takes the certification at face value and presumes that the attendant notice to the patent owner is complete and sufficient if certain basic requirements are met, the most substantive of which is the applicant's statement regarding the basis for the certification. *See* 21 C.F.R. § 314.95(c), (f). Whether the ANDA in fact infringes the patent owner's patent is irrelevant to the FDA's evaluation of the ANDA as this has nothing to do with the safety, efficacy, or security of the ANDA product.

Congress deliberately committed to the federal courts the adjudication of infringement claims that could impede the bringing of the generic drug to market, and, in doing so, surely intended that both the ANDA applicant defendant and the patentee plaintiff would receive the full benefit of the established rules of federal civil practice, including rules pertaining to discovery and notice pleading. To be sure, an ANDA applicant owes a "duty of care" in making its certification and providing the basis of that certification to the patent owner, but that duty, by statute, requires only an "opinion" by the ANDA applicant circumscribed by "the best of his knowledge" *at the time*. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Without the benefit of full discovery, the ANDA applicant's certification and statement are necessarily provisional. This provisional statement is all that is needed for the FDA to begin its evaluation of the ANDA and to provide the patent owner with enough information on which to decide whether it wishes to pursue an infringement claim against the applicant in litigation.

Over-reliance in litigation on the ANDA applicant's administrative certification and pre-litigation statement regarding the basis for the certification, as happened here, biases the court's fact-finding mission to resolve the case on the best available information. Particularly as the litigation *defendant*, the ANDA applicant is entitled to discovery to obtain critical non-public information necessary to its defense of the patent owner's infringement claim or invalidity defense. As noted in Mylan's petition, many defenses require non-public information available only through discovery. *See* Mylan's Pet. for a Writ of Cert. at 12-13 (explaining that components of invalidity and inequitable conduct defenses require non-public information available only from the patent owner through discovery).

Moreover, the Federal Rules of Civil Procedure contemplate that claims and defenses in litigation will evolve to conform to information learned through the discovery process and accordingly provide a system of notice pleading and liberal amendment of pleadings. *See* Fed. R. Civ. P. 15 (providing that a court should "freely" permit amendment of pleadings "when justice so requires," including "to conform [pleadings] to evidence and to raise an unpleaded issue"); *Oppenheimer Fund v. Sanders*, 437 U.S. 340, 351 (1978)

("Consistently with the notice-pleading system established by the Rules, discovery is not limited to issues raised by the pleadings, for discovery itself is designed to help define and clarify the issues. Nor is discovery limited to the merits of a case, for a variety of fact-oriented issues may arise during litigation that are not related to the merits.") (citing *Hickman v. Taylor*, 329 U.S. 495, 501 (1947)).

Precluding an ANDA applicant from developing its defenses during litigation and, if necessary based upon information developed subsequently in discovery, pursuing a defense not previously asserted in the certification and notice, is not only unfair, but, as Alphapharm points out, risks a violation of procedural due process. *See* Alphapharm's Pet. for a Writ of Cert. at 7-8; *Lindsey v. Normet*, 405 U.S. 56, 66 (1972) ("Due process requires that there be an opportunity to present every available defense.").

B. The Federal Circuit's Basing an Exceptional Case Fee Award on an ANDA Applicant's Assertion of Additional Defenses in a Hatch-Waxman Patent Infringement Action Will Undercut the Societal Benefit of the Generic Drug Market, in Frustration of Congressional Intent.

The Federal Circuit's error in affirming an exceptional case fee award that conflated the administrative ANDA process and the defense of the infringement action undermines the deliberate separation in the Hatch-Waxman Act of these two procedures. Accordingly, the Petitioners' were denied the full benefit of the Federal Rules of Civil Procedure

in presenting their best available defenses based upon information obtainable in discovery that was not available at the time of the ANDA certification. The Federal Circuit's flawed ruling has far-reaching negative effects that will do systemic harm to the generic drug approval process.

"In support of the American rule, it has been argued that since litigation is at best uncertain one should not be penalized for merely defending or prosecuting a lawsuit. . . ." *Fleischmann Distilling Corp. v. Maier Brewing Co.*, 386 U.S. 714, 717 (1967). Moreover, the finding of an exceptional case does not necessitate the award of attorney's fees under Section 285 of the Patent Act. *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.*, 781 F.2d 198, 201 (Fed. Cir. 1986). Rather, a court should use the special fee-shifting provision of Section 285 only where doing so may serve as an "instrument of justice." *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1197 (Fed. Cir. 1996).

For ANDA applicants, the normal expense of patent litigation is already a significant cost that restrains applicants from filing ANDAs without deliberate consideration of the merits of all potential defenses. The economics of litigation under the American rule already provide a strong incentive to ANDA applicants to have a good faith belief that they will prevail on their defenses. Based on input from the GPhA membership, a successful patent challenge in litigation is, at best, a 50/50 proposition. ANDA applicants have strong business incentives to pursue only those litigations where they are likely to prevail. It makes no sense to incur the cost of litigation if the ANDA applicant has no

chance of avoiding the patent and making and selling the drug. Nevertheless, when preparing its ANDA certification, the only information regarding the listed patents available to the applicant is that in the public domain. Without non-public information from the patent owner, the ANDA applicant can never completely confirm its theories of invalidity or non-infringement.

The Federal Circuit's ruling here will only frustrate the purpose of the Hatch-Waxman Act by increasing the costs of getting generic drugs to market. Under the reasoning of the Federal Circuit's ruling, ANDA applicants will have no choice but to continue to pursue defenses alleged in their certifications even after learning information during discovery that would otherwise serve to focus the litigation on the most meritorious defenses. Such precedent will not only increase the costs to the individual litigants, but will also waste judicial resources and may serve as a deterrent for some ANDA applicants to even challenge patents on certain products. Changing defenses during the course of discovery is ordinary and should be permitted, not condemned.

There are several legitimate reasons why litigants change defenses during litigation. For example, discovery may reveal more pertinent prior art on which to base an invalidity defense than that which was cited in the ANDA certification. Discovery may also reveal a basis for a best mode or inequitable conduct defense that was not known previously. Additionally, discovery may produce information that makes an element of a previously asserted defense more difficult to prove and,

accordingly, a litigant may withdraw that defense in litigation.

Moreover, where a litigant misuses procedural rules and commits litigation misconduct, the narrower remedy of sanctions under Federal Rule of Civil Procedure 37 is more appropriate than fee-shifting. *See* Fed. R. Civ. P. 37(b). In fact, "when there is bad-faith conduct in the course of litigation that could be adequately sanctioned under the Rules, the court ordinarily should rely on the Rules rather than [its] inherent power." *Chambers v. NASCO, Inc.*, 501 U.S. 32, 50 (1991). Even where Rule 37 sanctions are not sufficient, the court should use its inherent power conservatively. *See FDIC v. Conner*, 20 F.3d 1376, 1383 (5th Cir. 1994) (noting that sanctions should be "narrowly tailored to serve only their necessary function").

An award of nearly $17 million in attorney's and expert fees, as happened here, is excessive and not justified. Such an application of the fee-shifting exception to the American rule is not an "instrument of justice." The message sent by the Federal Circuit's ruling in this case will deter ANDA applicants from asserting the best possible legal theories in litigation and this chilling effect will deprive the courts of meritorious defenses and hamper the accessibility of affordable life-saving and life-improving drugs to the public.

CONCLUSION

The Federal Circuit wrongly concluded that the district court properly deemed this case exceptional "based on the specific circumstances involved in this case, *viz.*, baseless certification letters compounded with litigation misconduct." Pet. App. 16a. By glossing over the district court's inappropriate reliance on Petitioners' ANDA certifications, the Federal Circuit opened the doors for patent owners to use every step of the FDA's *administrative* approval process to demonstrate bad faith on the part of the ANDA applicant during civil *litigation*. Contrary to the Hatch-Waxman Act and rules of our federal judicial system, the $16.8 million fee award in this case has the effect of placing an unreasonable burden on ANDA applicants in submitting ANDAs to the FDA and putting ANDA applicants in an unfair and untenable position in litigation.

The petitions for writs of certiorari should be granted.

Respectfully submitted,

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